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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF UNDER SEAL	No. 10 CIV 5645 (MGC)
v.	**FILED UNDER SEAL**
DEFENDANT UNDER SEAL	**SECOND AMENDED COMPLAINT AND JURY DEMAND**

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* JOHN A. WOOD, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, the Commonwealth of MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, the Commonwealth of VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, *Plaintiffs*, v. ALLERGAN, INC., *Defendant*.	No. 10 CIV 5645 (MGC) **FILED UNDER SEAL** **SECOND AMENDED COMPLAINT AND JURY DEMAND**

TABLE OF CONTENTS

SECOND AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America and the *Qui Tam* States by John A. Wood ("Relator"), by and through his attorneys, against Defendant Allergan, Inc. ("Allergan," "Defendant," or "Company"), pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, and pursuant to the *qui tam* provisions of the following states: the California False Claims Act, Cal. Gov't Code § 12650 *et seq.* (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.*(2010); the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.* (2010); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.* (2000); the District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.* (2000); the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.* (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.* (2007); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.* (2006); the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.* (2000); the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.* (2007); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.* (2006); the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-601 *et seq.* (LexisNexis 2010); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.* (2007); the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.* (2007); the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.* (2011); the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.* (1999); the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.* (2007); the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.* (West 2007); the New Mexico Medicaid False Claims Act, N.M.

Stat. Ann. § 27-14-1 *et seq.* (2007); the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.* (McKinney 2010); the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.* (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.* (2007); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.* (2008); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.* (West 2006); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2011); and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.* (2007) ("State *qui tam* statutes" or "*Qui Tam* States").

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States and the *Qui Tam* States arising from false and/or fraudulent records, statements, and claims made, used and caused to be made, used or presented by Defendant and/or its agents, employees or co-conspirators under the False Claims Act and the State *qui tam* statutes.

2. Since at least 2003, Allergan has successfully maximized its profits through the payment of bribes, the illegal, off-label promotion of its pharmaceutical products, and the provision of hidden discounts to health care providers treating Medicaid and Medicare patients, in a concerted effort to maintain and increase market share. As part of its business model, Allergan directed its sales representatives (a) to provide free drugs, supplies, and consulting services in order to induce physicians to prescribe Zymar®, Zymaxid®, Acular LS®, Acuvail®, and Restasis®; and (b) to illegally promote its drugs Acuvail®, Zymar®, and Zymaxid® based on unsubstantiated superiority claims and/or for indications not approved by the Food and Drug Administration ("FDA").

3. As part of its widespread kickback scheme to induce physicians to prescribe its drugs, Allergan provided ophthalmologists with valuable products such as cataract surgery kits, which contained "free" prescriptions of multiple Allergan eye care drugs, including Pred Forte® (a topical steroid), Acular®/Acular LS®/Acuvail® (topical NSAIDs), and/or Zymar®/ Zymaxid® (topical anti-infectives). Allergan provided these kits contingent on health care professionals' agreement to prescribe its drugs, and closely monitored recipients' prescribing behavior to ensure that the Company was achieving a sufficient return on investment. An "Action Plan" distributed by Field Sales Trainer William Scruggs was indicative of the Company's calculation, and subsequent revocation of kits from practices that did not prescribe sufficient Allergan products in return: "No more kits till we see a better return."

4. Even after Allergan stopped providing kits due to compliance concerns, it continued to provide physicians with substantial amounts of free drugs in exchange for their agreement to prescribe additional Allergan products. Just as it had with its free kits, Allergan again closely monitored the quantity of free drugs it provided relative to the prescriptions written by the receiving physician, in order to ensure that the Company was achieving a sufficient return on investment. As a strong indication of the effectiveness these free products to induce physicians to prescribe Allergan drugs, when the Company announced in June 2010 that it would stop providing them due to compliance concerns, Allergan sales representatives expressed widespread fear that, in the absence of kickbacks, physicians would instead prescribe generic alternatives to Acuvail® and Zymaxid®.

5. Allergan also leveraged a litany of additional "resources" to induce physicians to prescribe its drugs. These included free patient instruction sheets and free pre-printed prescription pads, free reimbursement assistance through the "PARx" program, and free or

discounted business consulting services. The consulting services were at all times material hereto, and remain, a particularly integral part of Allergan's promotion of Restasis®, since they serve both as an outright inducement to physicians to prescribe the drug, as well as simultaneously facilitate the development of profitable "dry eye practices" with prescribing of Restasis® at their core. Allergan Eye Care Business Advisory Group ("ECBA") consultants provide physicians with wide-ranging advice, from how to maximize revenue and profitability in the overall practice, to how to set up, bill, code, and recruit patients for a dedicated dry eye section of the practice. ECBA consulting services are offered only to high-prescribers or those who agree to become high-prescribers of Allergan's products.

6. In addition to its widespread use of kickbacks, Allergan also increased sales of Acuvail®, Zymar®, and Zymaxid® by illegally promoting the drugs off-label. Since Acuvail®'s launch in 2009, Allergan has promoted the drug as superior to Acular®, Acular LS®, and their generic equivalents, despite a complete lack of substantive evidence to support this claim. Likewise, Allergan promoted Zymar® and Zymaxid® for use in pre- and post-cataract surgery for the prevention of endophthalmitis, despite the fact that the drugs are only approved for treatment of bacterial conjunctivitis (pink eye), and that there is no substantial clinical evidence that supports their effectiveness for prophylaxis of endophthalmitis.

7. Allergan knew that many (if not most) of the patients being treated with Zymar®, Zymaxid®, Acular LS®, Acuvail®, and Restasis® were Government Program beneficiaries, and it intended (a) that its provision of free goods would induce health care professionals to prescribe these drugs rather than cheaper and potentially more suitable alternatives; (b) that its untruthful and misleading off-label claims would cause health care professionals to prescribe these drugs rather than cheaper and potentially more suitable alternatives; and (c) that prescriptions resulting

from its kickbacks and misleading off-label claims would be submitted to the state and federal government by pharmacies. The claims which were submitted by these pharmacies, tainted by kickbacks and/or off-label claims, were false claims, and were reimbursed or paid for by Government Programs, such as Medicaid and Medicare Part D.

8. Defendant has, *inter alia*, knowingly (a) disregarded federal laws and FDA regulations relating to prohibitions on sampling, illegal kickback schemes, and off-label promotion; (b) improperly targeted physicians who do not treat bacterial conjunctivitis for the promotion of Zymar® and Zymaxid®; and (c) concealed the fact that shipments of free supplies and free samples of Pred Forte®, Acular LS®, Acuvail®, Zymar®, and Zymaxid® were illegally being traded in exchange for Acular LS®, Acuvail®, Zymar®, Zymaxid®, and Restasis® prescriptions.

9. From at least the launch of Zymar® in 2003, Defendant has failed to accurately report its Average Manufacturer Price ("AMP"), or Best Price, as required by the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, et seq., by engaging in the fraudulent schemes described herein. As a result, the Medicaid Program and the *Qui Tam* States have been deprived of the lowest price on the Allergan drug products, which Allergan provided to ophthalmologists at heavily discounted prices.

10. Allergan's conduct as described in this Second Amended Complaint also violated the "Stark Law," 42 U.S.C. § 1395nn, and 42 C.F.R. § 411.350 *et seq.* by providing inducements to physicians with which Allergan had a financial relationship to prescribe Allergan's outpatient drug products, including for off-label uses.

11. Defendant has violated the Federal Anti-Kickback Statute, the Federal False Claims Act, the Medicaid Rebate Act, the Stark Law, and/or the Federal Prescription Drug

Marketing Act, and in so doing, has cheated the Federal Government and the *Qui Tam* States out of hundreds of millions of dollars that should not have been paid, thereby unjustly enriching the Defendant.

II. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

13. This Court has personal jurisdiction over the Defendant because, among other things, Defendant transacts business in this District, and engaged in wrongdoing in this District.

14. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendant transacts business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

15. The causes of action alleged herein are timely brought because, among other reasons, of efforts by the Defendant to conceal from the United States its wrongdoing in connection with the allegations made herein.

III. PARTIES

A. Plaintiff/Relator John A. Wood

16. Plaintiff/Relator John A. Wood ("Relator Wood") is a resident of Canal Fulton, Ohio. He received a Bachelor of Science, Sports Management degree from Valparaiso University, Valparaiso, Indiana in May 1998. Relator Wood was employed by Defendant

Allergan as an ophthalmology sales representative from October 2008 to July 6, 2010, when he was unlawfully terminated as a result of his whistle-blowing activity.

17. While employed at Allergan, Relator Wood was a Senior Territory Manager in the Northeast Ohio district, where he sold external disease/dry eye surgical care kits and products to cataract, refractive, and retinal surgeons. Prior to joining Allergan, Relator Wood worked for Pfizer from 2003 to 2006 as a Cardiovascular Sales Representative, and from 2006 to October 2008 as a Therapeutic Sales Representative selling ophthalmic products.

18. Relator Wood held the title of Senior Territory Manager throughout his tenure at Allergan. In that capacity, Relator Wood called on health care professionals in his assigned territory and encouraged them to prescribe his assigned drugs, including Acular LS®, Acuvail®, Zymar®, Zymaxid®, and Restasis®. Relator Wood's compensation package was calculated as base compensation plus a bonus based on progress reaching a predetermined goal for monthly sales growth. In this way, Allergan tied sales representatives' compensation to the Company's sales growth and incentivized each sales representative to increase sales growth irrespective of the illegality of use of kickbacks and off-label marketing.

19. Relator Wood is an original source of the kickback, off-label promotion, and Medicaid Best Price allegations in this Second Amended Complaint, and these allegations are not based upon publicly disclosed information. He has provided the government with material information prior to the filing of this Second Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2), including electronic and hard copy documents; detailed internal Allergan databases, which tracked kickbacks to health care professionals throughout the United States and the impact of those kickbacks on prescribing behavior in connection with private and government program patients; and audio recordings.

20. Prior to filing this Second Amended Complaint, Relator Wood brought the wrongdoing described herein to the attention of Allergan. However, Allergan terminated Relator Wood's employment, following his disclosure of these allegations, in order to intimidate and retaliate against Relator Wood for his whistle-blowing activity.

B. Defendant Allergan, Inc.

21. Allergan is a Delaware corporation with its principal place of business at 2525 Dupont Drive, Irvine, California 92612. Allergan manufactures pharmaceutical and biological products, as well as medical devices, and employs some 8,000 people worldwide. Allergan has a large eye care division, which produces (or produced) prescription drugs including Acular®, Acular LS®, Acuvail®, Zymar®, Zymaxid®, Pred Forte®, and Restasis®, as well as over-the-counter Optive® and Refresh® artificial tears. These products treat a variety of eye conditions, including glaucoma, dry eye, and bacterial conjunctivitis. Allergan is a global leader in the eye care business and is one of the fastest-growing eye care companies in the world. For 2011, Allergan reported $5.35 billion in sales and $934.5 million in profit. In its fourth quarter 2011 earnings release, Allergan predicted full-year 2012 sales of $5.65 to 5.85 billion.

22. Brand-name prescription drug products sold by Allergan, including Acular®, Acular LS®, Acuvail®, Zymar®, Zymaxid®, Pred Forte®, and Restasis®, are paid or reimbursed by various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association ("BCBSA"); the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395 *et seq.*; via Medicare Part C, also known as Medicare+Choice; patients covered by Medicare Part D; the Indian Health Service; Medicaid; the Mail Handler's Health Benefit Plan ("MHHBP"); the U.S.

Secret Service Employees Health Association ("SSEH") Health Benefit Plan; the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"); and the Veteran's Health Administration ("VHA") (collectively, "Government Programs").

23. The Allergan sales teams are separated based on which products they promote. Allergan external disease/dry eye products, which include Acular®/Acular LS®/Acuvail®, Zymar®/Zymaxid®, Restasis®, and Optive®/Refresh® tears, are promoted by the Blue and Gold teams. Allergan glaucoma products, which include Lumigan®, Alphagan P®, Combigan®, Latisse®, Optive®, and Refresh® tears, are promoted by the Red and Silver teams.

24. Sales teams are further separated by geographic territory. Each territory includes four Territory Managers (i.e., sales representatives) whose responsibility it is to detail Allergan drugs to health care professionals. These four Territory Managers share responsibility for calling on the same accounts and are collectively referred to as a "Pod." Each Pod reports to an Area Manager, who is responsible for eight to twelve Territory Managers. There are 97 Pods in the country, representing 97 sales territories. Each territory is ranked 1 to 97 based on its success meeting its sales quota.

25. Area Managers report to Regional Sales Directors, who in turn report to Vice President of Sales for U.S. Eye Care, Dave LeCause. LeCause reported to Vice President of Sales Joseph Schultz, until Schultz retired June 2010. Schultz, in turn, reported to Vice President of North American Pharmaceuticals, Julian Gangolli, who reported to CEO David Pyott.

26. Since Blue and Gold representatives traditionally carry identical products, these teams work closely together and are ranked almost identically at any time. The same holds for the Red and Silver teams. Competition is therefore most pronounced within sales teams, among Pods. Territory Managers in the same Pod generally work together to share resources such as

samples, speaker program budgets, and lunch meetings with top accounts, to ensure that they are maximizing resources to achieve the best return on investment.

27. In addition to Territory Managers, Allergan employs Specialty Account Managers ("SAMs") to call on retinal specialists, large teaching institutions, and residency programs, where they promote the full line of Allergan products. There are about fifty Allergan SAMs nationwide, who report to SAM Area Managers. Their assigned geographic area generally overlaps multiple territories. In addition, there are twenty Regional Account Managers ("RAMs"), who are responsible for calling on managed care plans and securing favorable formulary status for Allergan's products. RAMs occasionally ride with Territory Managers to gain insight into how a product's formulary status affects sales.

IV. SUMMARY OF DEFENDANT'S ILLEGAL CONDUCT

A. The Purpose of the Fraudulent Kickback Scheme

28. It was the plan and purpose of Allergan's fraudulent kickback scheme, beginning at least as early as 2003 and continuing to the present, to provide free supplies, services, and drugs, including Pred Forte®, Acular®, Acular LS®, Acuvail®, Zymar®, and Zymaxid®, in order to induce physicians to prescribe additional Allergan drugs, including Acular LS®, Acuvail®, Zymar®, Zymaxid®, and Restasis® (hereinafter, the "Fraudulent Kickback Scheme"). These actions constitute violations of the Federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), in that they were taken to induce health care professionals to prescribe Acular LS®, Acuvail®, Zymar®, Zymaxid®, and/or Restasis® instead of cheaper and potentially more suitable alternatives.

29. The exchange of free drug samples to induce the prescribing of Allergan drug products also violated the Prescription Drug Marketing Act of 1987 (the "PDMA"), which

prohibits the sale, purchase, or trade of drug samples. As described herein, Allergan abused the purpose of the PDMA by supplying copious free amounts of its drug products, as trades for ongoing and future prescriptions.

30. These kickbacks were intended to, and did result, in the dispensing of Allergan's drugs and subsequent reimbursement by Allergan's customers, including Government Programs.

31. The payment and receipt of these kickbacks resulted in increased expense to Government Program customers insomuch as physicians would have, in the absence of Allergan's kickbacks, prescribed a cheaper generic competitor or no drug at all.

32. Allergan's provision of free supplies and drug products was made knowingly and with the intent to induce Government Programs to pay for Allergan's drug products. Allergan did so through a pattern of corrupt and illegal conduct in violation of the AKS, the PDMA, and the federal False Claims Act and State *qui tam* statutes.

B. The Purpose of the Fraudulent Marketing Scheme

33. It was the plan and purpose of Allergan's fraudulent marketing scheme to illegally market its drugs through off-label promotion, including but not limited to promotion of Acuvail® based on unsubstantiated superiority claims, and promotion of Zymar® and Zymaxid® for prevention of endophthalmitis in conjunction with cataract surgery (hereinafter, the "Fraudulent Marketing Scheme").

34. Allergan trained its sales force to promote Acuvail® as superior to Acular® and Acular LS®, as well as their generic equivalents, despite the total lack of evidence to support that claim. Allergan also instructed its sales force to promote Zymar® and Zymaxid® to cataract surgeons (who Allergan knew did not treat bacterial conjunctivitis) and trained sales representatives to tout Zymar® and Zymaxid® as effective prophylactics for endophthalmitis.

Allergan intended that, as a result of its off-label promotions, these health care professionals would write prescriptions for Acuvail®, Zymar®, and Zymaxid® that would be reimbursed by federal and state programs, including Medicaid and Medicare Part D.

35. By training and instructing its sales representatives to promote Acuvail®, Zymar®, and Zymaxid® off-label, Allergan's Fraudulent Marketing Scheme ultimately caused false and fraudulent statements to be made, and caused false and fraudulent claims to be submitted for payment by Government Programs. This was precisely what Allergan had intended, in order to maximize its profits. The Fraudulent Marketing Scheme is made in violation of the federal False Claims Act, 31 U.S.C. § 3729, and its state analogues.

C. The Manner and Means of Executing the Schemes

36. Allergan used its substantial sales force to increase sales of its drugs. From the beginning of Relator Wood's tenure at Allergan, he (and other new employees from various parts of the country) received training by Allergan to engage in the nationwide off-label and kickback schemes already being perpetrated by Allergan, which Relator Wood was told were intended to meet the competition to maximize profits. During his training, Relator Wood was instructed by Allergan to make misleading promotion to health care professionals, and offer kickbacks in order to increase sales of Allergan's drugs.

37. Relator Wood, like all of Allergan's sales force, was directed by management to implement Allergan's long-standing strategy, whereby Allergan routinely: (a) distributed numerous free "samples" of Pred Forte®, Acular LS®, and other Allergan drugs across the country, in order to induce physicians to prescribe greater quantities of Acular LS®, Acuvail®, Zymar®, and Zymaxid®; (b) provided ophthalmologists with free supplies such as patient care kits, patient instruction sheets, and preprinted prescription pads in exchange for their agreement

to prescribe Allergan drug products; (c) provided ophthalmologists with free or below-market rate consulting services in exchange for their agreement to prescribe Restasis® and/or other Allergan drug products; (d) misleadingly promoted Acuvail® as superior to competing formulations of ketorolac; (e) promoted Zymar® and Zymaxid® to health care professionals who did not typically treat patients suffering from bacterial conjunctivitis and initiated discussions about off-label uses of the product; and (f) trained health care professionals to evade insurance limitations on prescriptions for off-label uses. As part of its Fraudulent Kickback and Marketing Schemes, Allergan attempted to conceal these illegal inducements and off-label promotions to physicians.

38. Defendant Allergan's promotion of Acular LS®, Acuvail®, Zymar®, Zymaxid® and Restasis® involved the unlawful making of false records or statements and/or causing false claims to be submitted by pharmacies for the purpose of getting the false records or statements to bring about the Federal Government and *Qui Tam* States' payment of false or fraudulent claims.

39. Defendant's conduct had a material effect on the Governments' decision to pay for Allergan's drug products. Had the federal Government and *Qui Tam* States known that the prescriptions written for Allergan's brand-name drug products were the intended result of Defendant's unlawful activities, they would not have made such reimbursements.

40. Defendant has discontinued some aspects of the Fraudulent Kickback and Marketing Schemes. In its announcements of these discontinuations, Allergan acknowledged that its practices had been unlawful.

V. BACKGROUND OF DRUGS PROMOTED BY ALLERGAN

41. Allergan manufactures and markets drugs that treat various ophthalmic conditions, and many of its key customers are ophthalmologists. There are some 15,000

ophthalmologists in the United States, the majority of who perform eye surgeries, including cataract surgery. For use pre- and post-cataract surgery, ophthalmologists routinely prescribe topical steroids such as Pred Forte®, anti-infectives such as Zymar® and Zymaxid®, and non-steroidal anti-inflammatory drugs such as Acular®, Acular LS®, Acuvail®. Given the significant number of cataract surgeries performed each year in the United States, the market for surgery-related prescription drugs is substantial.

42. This market is also highly competitive. In addition to Allergan, Alcon, Inc. ("Alcon"), headquartered in Fort Worth, Texas, has a large market presence, selling products that compete head-to-head with Allergan's anti-infectives and NSAIDs. Together, Allergan and Alcon dominate the eye care drug market, each possessing approximately 50% of all cataract surgery-related drug sales.

43. Faced with intense competition from Alcon, and more recently from ISTA Pharmaceuticals, Allergan implemented increasingly aggressive — and illegal — strategies to maintain and gain market share. Allergan's strategy was simple: provide ophthalmologists free products, supplies, and services to win their business and stave off competition ("The Fraudulent Kickback Scheme"). At the same time, Allergan heavily promoted its drugs Acuvail®, Zymar®, and Zymaxid® off-label — Acuvail® based on unsubstantiated superiority claims, and Zymar® and Zymaxid® for the non-FDA-approved use of prevention of endophthalmitis in conjunction with cataract surgery ("The Fraudulent Marketing Scheme").

A. Acular®, Acular LS®, and Acuvail® (ketorolac ophthalmic solution, 0.5%, 0.4%, and 0.45%, respectively)

44. Acular® was originally approved on November 9, 1992, for treatment of allergic conjunctivitis. In November 1997, its indication was expanded to include treatment of post-surgical inflammation following cataract extraction.

45. On May 30, 2003, the FDA approved a new formulation of Acular®, branded Acular LS®, which contained ketorolac, the same active ingredient as the original Acular®, but at a reduced concentration of 0.4% instead of the original 0.5%. The FDA approved Acular LS® for the reduction of ocular pain and burning/stinging following corneal refractive surgery. Corneal refractive surgery corrects mild-to-moderate nearsightedness, and is also referred to as "LASIK surgery." Acular LS® is not approved for use in conjunction with cataract surgery.

46. Until it became available generically in September 2009, a 5 ml bottle of Acular LS® cost between $70 and $100. As part of its Fraudulent Kickback Scheme, Allergan provided Pred Forte® and other Allergan drugs to numerous ophthalmologists in exchange for their agreement to prescribe Acular LS®.

47. On July 22, 2009, immediately prior to the availability of generic Acular® and Acular LS®, the FDA approved Acuvail® for the treatment of pain and inflammation following cataract surgery. Acuvail® contains the same active ingredient (ketorolac) as Acular® and Acular LS®, but at a concentration of 0.45% — halfway between the 0.5% and 0.4% concentrations of Acular® and Acular LS®.

48. In order to stem the anticipated loss of revenue from Acular LS® as a result of generic competition, Allergan sought to convert all Acular LS® prescriptions to Acuvail®. To do so, Allergan implemented an off-label marketing campaign in which it claimed that Acuvail®

was clinically superior to Acular® and Acular LS®, despite the complete lack of substantive evidence supporting this claim. Just as it had done with Acular LS®, Allergan also provided Pred Forte® and/or other Allergan drugs to ophthalmologists in exchange for their agreement to prescribe Acuvail®.

B. Zymar® and Zymaxid® (gatifloxacin ophthalmic solution, 0.3% and 0.5%, respectively)

49. Zymar® was approved by the FDA on March 28, 2003, for the treatment of acute bacterial conjunctivitis caused by susceptible strains of aerobic Gram-positive bacteria *Cornyebacterium propinquum*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus mitis*, *Streptococcus pneumoniae*; or aerobic Gram-negative bacteria *Haemophilus influenzae*. Allergan licenses Zymar® from Kyorin Pharmaceutical Co., Ltd., and has worldwide ophthalmic commercial rights excluding Japan, Korea, Taiwan, and certain other countries in Asia and Europe.

50. When it was launched, Zymar® was the first "fourth generation" fluoroquinolone approved for treatment of bacterial conjunctivitis, and Allergan intended it as a replacement for its third-generation Ocuflox® (ofloxacin ophthalmic solution), which was about to lose patent protection.

51. Conjunctivitis (pink eye), one of the most common eye diseases worldwide, is an inflammation of the conjunctiva which may be of bacterial, viral, allergic, fungal or traumatic etiology. Most pediatric cases of conjunctivitis are caused by *Streptococcus pneumoniae* or *Haemophilus influenza*, and most adult cases are caused by *Staphylococcus* species. Untreated, conjunctivitis may last ten to fourteen days, but with proper treatment, it may be limited to one to three days.

52. The FDA's limited approval of Zymar® for bacterial conjunctivitis, however, substantially limited its sales potential. Sales pressure increased when Alcon's competing fluoroquinolone Vigamox® was approved in late 2003, also for treatment of bacterial conjunctivitis. In order to expand sales, Allergan illegally marketed Zymar® off-label for prevention of endophthalmitis in conjunction with cataract surgery.

53. In both the leading and most commonly available statutorily approved compendia, DRUGDEX and the American Hospital Formulary Service ("AHFS") Drug Information, there are currently no supported off-label uses for Zymar®.

54. To further drive sales, Alcon provided ophthalmologists, and particularly cataract surgeons, with free patient care kits that included Pred Forte® and/or other Allergan eye care products in exchange for their agreement to prescribe Zymar®.

55. In 2007, U.S. sales of Zymar® were $104,737,945.17, as reported by Chain Drug Review. Due to Allergan's aggressive off-label promotion and its payment of kickbacks, within ten weeks of its launch in April 2003, Zymar® became the most-prescribed ophthalmic fluoroquinolone, with the vast majority of its sales for off-label use. Allergan does not report annual sales of Zymar® in its SEC filings, but noted in its 2007 10-K that "[a]ccording to Verispan, an independent research firm, Zymar® was the number two ophthalmic anti-infective prescribed by ophthalmologists in the United States in 2007." Given the prevalent use of Zymar® in cataract surgery, and that most cataract patients are Medicare beneficiaries, a substantial portion of Zymar® sales were likely funded by Government Programs.

56. In addition to competition from Vigamox®, Allergan also faced the prospect of competition from generic versions of Zymar®. In 2007, Allergan and its Japanese licensors filed suit against generic pharmaceutical manufacturer Apotex, Inc., which had submitted an

Abbreviated New Drug Application to market generic versions of Zymar®. On June 14, 2010, the United States District Court for Delaware held that the '045 patent was invalid for obviousness. *See Senju Pharmaceutical Co. Ltd. v. Apotex Inc.*, 07-cv-779-SLR (D. Del.).

57. In order to mitigate competition from generic equivalents of Zymar®, Allergan sought approval for the follow-on product Zymaxid®, which the FDA approved on May 20, 2010, for treatment of bacterial conjunctivitis. Zymaxid® contains 0.5% gatifloxacin, compared to Zymar®'s 0.3% gatifloxacin.

58. Allergan continued both the Fraudulent Kickback and Marketing Schemes with regard to Zymaxid®, including (a) provision of free samples of Pred Forte® or other Allergan drugs in exchange for physicians' agreement to prescribe Zymaxid®; and (b) off-label promotion for prevention of endophthalmitis in conjunction with cataract surgery.

C. Pred Forte® (prednisolone acetate ophthalmic suspension, 1%)

59. Pred Forte® is an ophthalmic corticosteroid indicated for the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe. It was approved by the FDA on May 30, 1973.

60. A 10 ml bottle of Pred Forte® costs $68.06 at www.DrugStore.com. As part of its Fraudulent Kickback Scheme, Allergan provided ophthalmologists with free samples of Pred Forte® in exchange for their agreement to prescribe Zymar®, Zymaxid®, Acular LS®, and/or Acuvail®. The "free" sample of Pred Forte® was generally sufficient for the duration of the entire post-surgical regimen.

D. Restasis® (cyclosporine ophthalmic emulsion) 5%

61. On December 23, 2002, the FDA approved Restasis® to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation

associated with keratoconjunctivitis sicca. Keratoconjunctivitis sicca — also known as dry-eye syndrome — is a disease in which dryness results in inflammation of the cornea and/or conjunctiva. Restasis® was the first prescription drug approved for treatment of dry eye, which had previously been treated primarily by over-the-counter artificial tears.

62. Net worldwide sales of Restasis® were $697.1 million in 2011, $620.5 million in 2010, $522.9 million in 2009, $444.0 million in 2008, $344.5 million in 2007, $270.2 million in 2006, $190.9 million in 2005, and $99.8 million in 2004. Most of these sales were in the U.S. Total Medicaid reimbursements from 2003 (Q3) to 2010 (Q3) were $215,773,942.81.

63. In order to overcome the prevalence of artificial tears for the treatment of dry eye, Allergan provided valuable consulting and reimbursement services to induce ophthalmologists to prescribe Restasis®, and to make treatment of dry eye a key part of their practices.

VI. BACKGROUND OF THE REGULATORY FRAMEWORK

A. The Food and Drug Administration ("FDA") Regulatory System

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

64. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

65. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs")

must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

66. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *See* 21 U.S.C. § 321. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

67. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well-defined and reliable methods of assessing subjects' responses to treatment. *See* 21 C.F.R. § 314.26.

68. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally

intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research ("CDER"), Center for Biologics Evaluation and Research ("CBER"), *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products*, May 1998; *see also* Final Decision on Benylin, 44 FR 51512, 518 (Aug. 31, 1979). FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of other doses and regimens, dosage forms, stages of disease, populations, or endpoints, to support a single adequate and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

69. In other cases, FDA has relied on only a single, adequate and well-controlled efficacy study to support approval – generally only in cases in which a single multi-center study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds. In section 115(a) of the Modernization Act, Congress amended

section 505(d) of the Act to make it clear that the Agency may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

70. Cases in which the FDA has approved a drug on the basis of one clinical trial plus confirmatory evidence are rare. They include instances of large, independently conducted multi-center trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

71. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off-Label Marketing and False and Misleading Statements About a Drug's Use.

72. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels – including all marketing and

promotional materials relating to the drug – may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

73. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

74. A manufacturer, like Allergan, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

75. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or

frequency than specified on the label or treating a different patient population, e.g., treating a child when the drug is approved to treat adults.

76. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug-company-sponsored continuing medical education ("CME") courses and speaker programs, and drug-company-sponsored clinical trials.

77. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final

Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

78. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below.

79. Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See* 21 C.F.R. 202.1(e)(6)(xi); *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

80. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6) *et seq*. ban advertisements that are false, lacking in fair balance, or otherwise misleading. The use of unsubstantiated comparative claims also is prohibited by law. *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Allergan may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safe as or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Federal Programs, including Medicare Part D and Medicaid.

81. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles

or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. 202.1(e)(6)(iv).

82. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. 202.1(e)(5) *et seq*. A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

83. Section 202.1(1)(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug. 21 C.F.R. 202.1(1)(2)

84. Section 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." 21 C.F.R. 201.56

85. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

86. Section 21 C.F.R. 99.101 *et* seq. lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to

evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

87. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. 99.101(a)(4).

88. Off-label information may be disseminated only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination, and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

89. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The FDA Has Limited Ability To Regulate Drug Maker Marketing and Promotion.

90. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off-label uses. *See* Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

91. DDMAC's effectiveness in regulating off-label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-approved. FDA review of promotional materials occurs, if at all, only after the materials already have appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading or unbalanced materials. *Id.*

92. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

93. The FDA's ineffectiveness in policing off-label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an

average of seven (7) months to issue letters in response to off-label promotions. *See Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (GAO 08-835), http://www.gao.gov/new.items/d08835.pdf. Among the Report's findings: (1) FDA does not have separate oversight activities to specifically capture off-label promotion; (2) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (3) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (4) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives; (5) during calendar years 2003 through 2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

B. The Anti-Kickback Statute

94. The federal Anti-Kickback Statute ("AKS") prohibits any person from knowingly and willfully offering to pay any remuneration to another person to induce the purchase, order, or recommendation of any good or item for which payment may be made in whole or in part by the Medicare program. 42 U.S.C. § 1320a-7b(b). In addition to criminal penalties, violations of the AKS may result in civil monetary penalties of up to $50,000 per violation, an assessment of up to three times the amount of remuneration paid, and exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7a(7). These substantial penalties reflect the significance of the prohibition against kickbacks as a critical tool in the fight against health care fraud. *See* H. Rep. 95-393, 95th Cong., 1st Sess. at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3047 (making violations of AKS a felony, and explaining that fraud in federal health care

programs "cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government sponsored program").

95. As long as one purpose of the offer to pay or payment of remuneration to induce the purchase, order, or recommendation of any good or item for which payment may be made in whole or in part by the Medicare program, the AKS has been violated. For example, Allergan could not lawfully offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program, even if the remuneration has some benefit to patients, as long as one purpose of the remuneration was the inducement of a physician to write additional prescriptions for Allergan's pharmaceutical products.

96. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices that violate the Anti-Kickback law. *Special Fraud Alert: Prescription Drug Marketing Schemes*, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the suspect practices cited by the Inspector General were drug companies' payments to physicians who had offered no particular services of benefit to the drug company but who had generated in the past, or had the potential to generate in the future, a large volume of business for the drug company. *Id.*

97. In May 2003, the Inspector General of HHS released a further Guidance identifying in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" infecting federal health care programs. *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003) ("2003 Guidance"). The 2003 Guidance cautions manufacturers against engaging in the

following suspect practices, including providing improper business courtesies and other gratuities, such as gifts such as merchandise of more than trivial value, entertainment, recreation, travel, meals, and other gratuities furnished in association with information or marketing presentations. *Id.* at 23731-39.

98. In addition, the 2003 Guidance stresses that "under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)." *Id.*

99. Notably, as part of the comprehensive health care reform legislation enacted earlier this year, Congress amended the AKS to expressly clarify that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. 1320a-7b(g)).

100. Compliance with the AKS is a cornerstone for reimbursement under Medicare and Medicaid because kickbacks destroy an essential premise upon which the reimbursement of all health care claims depends: that the medical services, devices, or drugs are being furnished because they are medically necessary for the patient and not simply because they advance the financial interests of the ordering physician.

101. Reimbursement from Medicare and other federal health insurance programs requires compliance with the AKS. The FCA imposes liability not only for the direct submission of false claims to the government, but also for causing others to make claims for payment to which they are not entitled. Thus, the FCA not only prohibits the knowing presentation of claims that do not satisfy all relevant conditions of payment, it also prohibits end-runs around these

requirements in which one person knowingly causes another person to submit ineligible claims to the government – where the submission of ineligible claims for reimbursement under federal health care programs is the natural consequence of the defendant's actions.

102. As described in this Second Amended Complaint, Allergan's kickback scheme caused pharmacies and others to submit ineligible claims, since the prescription claims tainted by the kickbacks were false, and were integral to a causal chain leading to payment by Government Programs.

C. Prescription Drug Payment Under Federal Health Care and Other Programs

103. Whether an FDA-approved drug is approved for a particular indication (*i.e.,* use) determines whether a prescription for that use may be properly reimbursed by Government Programs.

1. The Medicaid Program

104. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments.

105. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2)-(3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3). These drugs may also include, in some instances, over-the-counter ("OTC") drug products.

106. A medically-accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6). During the time period relevant to this Second Amended Complaint, Allergan promoted off-label uses of Zymar® and Zymaxid® that were not eligible for reimbursement from Medicaid because the off-label uses were neither listed in the FDA-approved labeling nor included in any of the drug compendia specified by the Medicaid statute.

107. Between 2003 and 2010, Medicaid reimbursed for more than 1.5 million prescriptions of Zymar®.

2. The Medicare Program

108. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

109. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k), as described above.

110. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies.

111. During the time period relevant to this Second Amended Complaint, Allergan promoted off-label uses of Zymar® and Zymaxid® that were not eligible for reimbursement from Medicare because the off-label uses were neither listed in the FDA-approved labeling nor included in any of the drug compendia specified by the statute.

3. Reimbursement under Other Federal Health Care Programs

112. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs. For example:

(i) CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces.

(ii) CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100% service-connected disabilities.

(iii) The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and it is administered by the Office of Personnel Management.

Coverage of off-label drug use under these programs is similar to the coverage provided by the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

113. During the time period relevant to this Second Amended Complaint, Allergan's provision of kickbacks and promotion of off-label uses of Zymar® and Zymaxid® to ophthalmologists resulted in the prescribing of Acular® LS, Acuvail®, Zymar®, Zymaxid®, and Restasis® for Government Program patients, which caused false claims to be submitted to

Government Programs, which claims were simply not eligible for reimbursement under any of the various state and federal health care programs.

D. Medicare/Medicaid Reimbursement for Cataract Surgery

114. Cataracts affect more than 20 million people in the United States and are the number one line-item cost of Medicare reimbursement. According to the National Eye Institute, in the United States, cataract surgery is the most frequently performed surgical procedure among 30 million Medicare beneficiaries. Approximately 1.35 million cataract operations are performed annually at an estimated cost of $3.5 billion.

115. Cataracts, which can have devastating effects on the eye, affect 42 percent of the population between the ages of 70 and 80, and 68 percent of the population over the age of 80. By age 80, more than half of all Americans either have a cataract or have had cataract surgery. Among Medicare beneficiaries, cataract is the most common condition for which eye care services are sought, accounting for 43 percent of visits to ophthalmologists and optometrists combined.

116. Allergan knew that the market for eye care drugs used in conjunction with cataract surgeries presented significant opportunities to increase sales, particularly for drugs prescribed to Medicare and/or Medicaid beneficiaries.

E. Allergan Adopts PhRMA and AdvaMed Codes on Gifts to Health Care Professionals

117. In 2002, the Pharmaceutical Research and Manufacturers of America adopted its *Code on Interactions with Healthcare Professionals*, or the "PhRMA Code," as updated in July 2008 and effective in January 2009. The PhRMA Code purportedly seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry

and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The most recent revisions to the PhRMA Code, effective January 2009, restrict or prohibit many activities previously permissible under the prior PhRMA Code by: prohibiting any entertainment or recreational events for non-employee health care professionals, including strict limitations on meals with physicians; eliminating non-educational business gifts; restricting speaker programs; and clarifying conditions on continuing medical education funding. The updated PhRMA Code also requires that pharmaceutical companies train their representatives on all applicable laws, regulations and industry codes governing interactions with health care professionals. Complying with the PhRMA Code is not a guarantee that a company is in compliance with the law.

118. In addition, the Advanced Medical Technology Association's Revised Code of Ethics, or the "AdvaMed Code," also seeks to ensure that medical device companies and health care professionals have collaborative relationships that meet high ethical standards; medical decisions are based on the best interests of patients; and medical device companies and health care professionals comply with applicable laws, regulations and government guidance. The AdvaMed Code was updated in December 2008 and became effective in July 2009. The revisions generally follow the 2008 changes in the PhRMA Code and include limitations on consulting arrangements, entertainment, meals, and gifts, among other areas. Complying with the AdvaMed Code is not a guarantee that a company is in compliance with the law.

119. Although Allergan states in its financial statements that its Board of Directors has "adopted and implemented a compliance program which it believes satisfies the requirements of these laws, regulations and [PhRMA and AdvaMed] codes," as set forth herein, it has

nonetheless concealed its widespread violations of even its own compliance program in its marketing of its drugs to health care professionals.

F. Allergan Views Off-Label Promotion as Permissible Free Speech and Sued FDA to Allow it to Off-Label Promote Botox®

120. Allergan's views on off-label promotion are clear, as evidenced by a lawsuit it filed on October 1, 2009, against the FDA, alleging that the U.S. government's ban on off-label marketing violates its First Amendment right to free speech. The lawsuit against the FDA sought to allow Allergan to present off-label information concerning its drug Botox®.

121. Allergan's suit did not challenge the Government's ability to prohibit pharmaceutical sponsors from disseminating false or misleading information about their products. Rather, the lawsuit only sought to permit Allergan to proactively provide the medical community with truthful, important information about common off-label uses of BOTOX®.

122. On August 31, 2010, Allergan agreed to plead guilty and pay $600 million to resolve its criminal and civil liability, and agreed to dismiss its lawsuit.

123. Unlike in the Botox® litigation, where Allergan argued it should be allowed to give "truthful," though off-label, information because such off-label information is supported in the clinical research and the compendia, here Allergan has no such defense. There is neither substantial clinical evidence nor compendia support for use of Zymar® or Zymaxid® to prevent endophthalmitis in conjunction with cataract surgery. Likewise, there is no evidence that Acuvail® is clinically superior to Acular® or Acular LS®. At no point did Allergan petition the government for permission to provide such information to health care professionals. Instead, Allergan pursued a unilateral misbranding strategy, combined with a kickback scheme, to

establish Zymar®, and subsequently Zymaxid®, as the standard of care in cataract surgery, and to convince physicians to "upgrade" all Acular LS® patients to Acuvail®.

VII. THE FRAUDULENT KICKBACK SCHEME WITH REGARD TO ACULAR LS®, ACUVAIL®, ZYMAR®, ZYMAXID®, AND RESTASIS®

A. Allergan Gives Away Free Products and Services to Induce Ophthalmologists to Prescribe Allergan Products, Resulting in Improper Government Program Reimbursements

124. In order to increase sales and profits, Allergan planned and engaged in a Fraudulent Kickback Scheme through which it induced physicians to prescribe its drug products, including Zymar®, Zymaxid®, Acular LS®, Acuvail®, and Restasis®. The Fraudulent Kickback Scheme was, and with regard to certain components still remains, a multi-faceted program to buy business in exchange for free products, supplies and services, including:

- Free "Custom Care Kits";
- Free drugs;
- Free customized patient instruction sheets;
- Free customized, pre-printed prescription pads for Allergan drugs;
- Free and below-market-rate consulting services; and
- Free reimbursement assistance.

125. Allergan knew that the Fraudulent Kickback Scheme was illegal. Its own compliance policy prohibits employees from using samples as an inducement to health care professionals to prescribe the Company's products:

> Allergan employees may never provide samples to induce a health care professional to purchase, prescribe or recommend Allergan products, or to reward a health care professional for doing so. In other words, providing samples based on a health care professional's past or future prescribing habits is strictly prohibited. In addition, samples of one Allergan drug may never be

> provided to induce the prescribing or purchasing of another Allergan drug.

Allergan U.S. Health Care Law Compliance Program: Policies and Procedures 2008 (the "Compliance Manual") at 98.

126. Nonetheless, as described below, Allergan systematically violated both its own compliance policy and the law by making the provision of kickbacks the centerpiece of its strategy to increase sales of its drugs. It did so in order to both organically grow sales, as well as to take market share from competitors Alcon and ISTA, in a single-minded strategy to induce physicians to prescribe its drugs.

127. Allergan's managers were not only aware of but were integral drivers of the Fraudulent Kickback Scheme, training and instructing sales representatives to leverage product samples, Custom Care Kits, and other free goods to grow sales. For example, in an email sent to his district on April 24, 2009, Area Manager Jon Weidner instructed sales representatives to "Leverage Pred-Forte!!!!!!!!!!!" in order to drive sales of Acular LS®. Emphasizing even more explicitly that samples of Pred Forte were intended as an inducement *in exchange* for physicians' agreement to prescribe Acular LS®, Weidner continued, "Pred [Forte] costs at least 40-50 bucks per bottle," so we want to not "just leave it lying around" but instead "[m]ake sure we are getting a return for our investment."

128. In another email, dated October 19, 2009, Weidner sent sales representatives in his district a memorandum including a list of "Senior Training Best Practices," which Weidner received during training at Allergan headquarters in Irvine, California. The memo discusses optimal use of "[r]esources" (i.e., kickbacks) to induce physicians to prescribe Allergan's drugs, and when to best "[p]ull out resources" (i.e., stop providing kickbacks) so as not to waste them

on physicians who do not prescribe Allergan drugs. Per the memo, "[t]here may come a time when the resources you provide to an office don't have an ROI [return on investment], so when do you pull out?" As managers were trained, the "best practice" was to "[a]ffix a dollar amount to what you provide in terms of sampling and demonstrate the cost to the office indicating that you want to help the office but you need to see [prescriptions] for acuvail and/or zymar [sic]." The memo demonstrates the nationwide reach of Allergan's Fraudulent Kickback Scheme.

129. Each of the preceding examples is indicative of Allergan's common and widespread use of kickbacks, which resulted in prescribing of Allergan's drugs for Government Program patients, causing false claims to be submitted to state and federal governments. Frequently, as in the above examples, managers were explicit in telling sales representatives that the Company's provision of free goods was contingent on receiving prescriptions from physicians in return. In other instances, the instruction was implicit. Whether explicit or implicit, however, it was always clear to sales representatives — who in turn made it clear to health care professionals — that Allergan would only provide free products, including drugs, Custom Care Kits, and consulting services, to physicians who agreed to prescribe and continue prescribing its products in return. For physicians who did not prescribe Allergan products in sufficient quantity or stopped prescribing them altogether, Allergan refused to provide, and in many instances even revoked, its provision of these free products.

130. Allergan's offer of kickbacks, as well as its actual provision of kickbacks, was made knowingly and with the intent to induce physicians to write prescriptions for its drug products that were then reimbursed by Government Programs, through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729. Moreover, Allergan's kickbacks caused pharmacies and others submitting claims to the Government to

falsely certify compliance with applicable laws and regulations, including that the claims were not tainted by illegal kickbacks.

131. Allergan knowingly and willfully offered and provided illegal remuneration in violation of the AKS, 42 U.S.C. § 1320a-7b(h)(2). As a result, Government Programs paid or reimbursed for prescriptions of Allergan products otherwise ineligible for payment or reimbursement.

132. As a result of these kickbacks, Government Programs have suffered significant damages.

B. Using Custom Care Kit Agreements to Bribe Health Care Professionals

133. Beginning as early as the year 1994, and continuing through December 2008, Allergan designed and implemented a scheme to bribe health care professionals, and particularly cataract surgeons, by giving them free patient care kits in exchange for prescribing Allergan drugs. Because the vast majority of cataract patients are Medicare beneficiaries, a substantial portion of these drugs were reimbursed by Government Programs.

134. The patient care kits that Allergan provided to health care professionals were referred to internally as "Custom Care Kits" ("CCKs"). CCKs were housed in a blue or black, leather or nylon bag, which frequently had the name of the ophthalmology practice printed on the side. The customized bags included varying combinations of the following items: a "trade-sized" 10 ml sample of Pred Forte®, the quantity of which was sufficient for an entire pre- and post-surgical regimen of care; a sample of Acular LS®; a sample of Zymar®; a sample of Optive® or Refresh® artificial tears; protective sunglasses for post-surgical use; a protective eye shield; tape and gauze to construct a protective eye patch; and an over-the-counter analgesic such as Tylenol

or Advil. The precise makeup of the kits was chosen by the individual ophthalmologist, based on a menu of options, in consultation with Allergan.

135. In most instances, a CCK was provided to the patient by a surgical counselor or coordinator during a pre-surgical visit. The patient then brought the kit back to the office for the actual surgery, as well as any post-surgical appointments. In many instances, patients who scheduled cataract surgery for their second eye for a date shortly following surgery for the first eye, returned for the second surgery with the same kit from their first surgery. In other instances, physicians provided a new kit for each surgery.

136. To order CCKs, an ophthalmologist coordinated with an Allergan sales representative, who submitted a "Custom Care Kit Agreement" ("CCK Agreement") on behalf of the ophthalmologist. The CCK Agreement consisted of a one page form, which Allergan provided to sales representatives, including Relator Wood, for the purpose of providing free CCKs to ophthalmologists. The CCK Agreements were periodically updated, and included printing on the bottom left-hand portion that identified the version, such as "APG 3744 REV. A 7/05 MDR." The bottom right-hand portion included the Allergan marketing department facsimile number, "MARKETING FAX (714) 796-3298," to which Allergan sales representatives submitted the completed forms.

137. Allergan sales representatives generally worked with the surgical coordinator or counselor to determine the mix and quantity of free medications and other goods that an individual practice would receive. Sections II and III of the CCK Agreement included a menu of options that allowed ophthalmology practices to choose among different versions of CCKs. There were twelve different kits, or "Kit Configurations," including, for example, "Cataract Kit A," "Cataract Kit #6," and "LASIK Kit A". Medication options included Acular®, Acular LS®,

various sizes of Pred Forte®, and "other." Sales representatives and ophthalmologists frequently used this "other" section to order over-the-counter artificial tears. Practitioners could also order other surgery-related supplies for inclusion in the kits, such as eye patches, paper or plastic tape, gauze, eye wash, eye shields, and/or sunglasses.

138. Most ophthalmology practices ordered all kits of a single configuration; however, some ophthalmologists, such as Dr. Paul Turgeon of Canton, Ohio, ordered multiple different versions of Custom Care Kits. In certain instances, for its best customers, Allergan agreed to provide a limited number of kits with "additional" drugs or other products, above those that it provided in its standard CCKs.

139. Section IV of the agreement denoted the "MONTHLY FORECAST" and "MAXIMUM 6 MONTH QUANTITY" of CCKs that the practice expected, and that Allergan allowed the practice, to use. The monthly forecast and six-month maximum quantity were generally based on the monthly number of cataract surgeries performed per month in the entire clinic, not solely by the health care professional who signed the agreement.

140. Section IV of the CCK also included a blank line to fill in the "PRICE PER KIT." In every example witnessed by Relator Wood during his employment with Allergan, the price per kit was always either marked as "0" or left blank.

141. Orders for CCKs were filled by Allergan's facility in Waco, Texas, through its subsidiary, Allergan Sales LLC, which is located at 8301 Mars Drive, Waco, Texas 76712. Shipping costs for the kits were paid by Allergan.

142. Allergan's ophthalmologist customers regarded CCKs as valuable, since competing ophthalmologists provided their patients with similar kits, including ones provided by Alcon. Thus, not having these kits would place an ophthalmologist at a competitive disadvantage

in the increasingly competitive market for cataract surgery patients. CCKs therefore served as a valuable and essential marketing tool, which Allergan provided for free to induce sales. In the absence of free kits from Allergan, ophthalmologists would need to purchase kits themselves, which, following Allergan's discontinuation of free CCKs in November 2009, they eventually did.

143. The following is a list of CCK Agreements, which provides a sample of physicians to whom Allergan provided CCKs in Relator Wood's territory, with the intent to induce them to prescribe its products:

Name & Address of Physician or Practice	Contract No. & Expiration Date	Effective Dates of the Agreement	Free Drugs Provided in Kits
Andrew C. Pederzolli, MD 1059 E. State St. Salem, OH 44460	Contract No.: 0480041809 Expired: 4/24/2008	5/01/08-11/01/08	Pred Forte Acular LS
Belmont Eye Clinic 3020 Belmont Ave. Youngstown, OH 44505	Renewal of Agreement Contract No.: 0480049512 Expired: 10/02/2008	9/25/08-2/25/09	Pred Forte Acular LS
Canton Ophthalmology 2600 W. Tuscarawas, #200 Canton, OH 44708	Renewal of Agreement Contract No.: 0500056290 Expired: 9/28/2005	9/29/05-3/29/06	Pred Forte
Clear Choice Laser 6960 S. Edgerton Rd. Brecksville, OH 44141	Renewal of Agreement Contract No.: 0480028013 Expired: Not Listed	7/16/08-1/16/09	Pred Forte Refresh Plus
Cleveland Eye Clinic 2740 Carnegie Ave. Cleveland, OH 44115	Renewal of Agreement Contract No.: 0480046998 Expired: 8/18/2008	10/01/08-3/01/09	Pred Forte Acular LS
Fladen Eye Center 1330 Timken Mercy Dr. NW, #310 Canton, OH 44708	Renewal of Agreement Contract No.: 0480041914 Expired: Not Listed	7/31/08-2/28/09	Pred Forte Refresh Plus
Fladen Eye Center 1330 Timken Mercy Dr. NW, #310 Canton, OH 44708	Renewal of Agreement Contract No.: 0480036753 Expired: Not Listed	1/07/08-7/7/08	Pred Forte Acular LS
Jeffrey Augustine 6960 S. Edgerton Brecksville, OH 44141	Contract No.: 0480035010 Expired: Not Listed	12/10/07-5/10/08	Pred Forte Refresh Plus Optive
Lasik Plus 6800 Rockside Rd, #A Independence, OH 44131	Renewal of Agreement Contract No.: 0480026425 Expired: Not Listed	3/21/07-9/21/07	Pred Forte Refresh Plus
Martuccio Eye Care 302 Niles Cortland Rd. Warren, OH 44484	New Kit Agreement Contract No.: Not Listed Expired: Not Listed	1/10/08-6/10/08	Pred Forte

Name & Address of Physician or Practice	Contract No. & Expiration Date	Effective Dates of the Agreement	Free Drugs Provided in Kits
Ohio Eye Alliance 985 S. Saw Burg Ave. Alliance, OH 44601	Renewal of Agreement Contract No.: 0480049211 Expired: Not Listed	9/15/08-2/15/09	Pred Forte Acular LS
Ophthalmic Physicians, Inc. 9485 Mentor Ave., #110 Mentor, OH 44060	Renewal of Agreement Contract No.: 0480049215 Expired: 10/01/2008	10/20/08-4/20/09	Pred Forte Acular LS
Paul Turgeon 1330 Mercy Dr. NW, #406 Canton, OH 44708	Renewal of Agreement Contract No.: 0480050683 Expired: 10/07/2008	9/30/08 – 2/28/09	Pred Forte Acular LS
Retina Associates 4690 Munson St. NW, #C Canton, OH 44718	Contract No.: 0480035199 Expired: Not Listed	1/11/08-6/11/08	Pred Forte
Summit Ophthalmology 1 Park West Blvd., #150 Akron, OH 44320	Renewal of Agreement Contract No.: 0480036082 Expired: Not Listed	12/10/07-5/10/08	Pred Forte Acular LS
TLC Center 6500 Rockside Rd., #100 Independence, OH 44131	Renewal of Agreement Contract No.: 0500058179 Expired: Not Listed	5/10/06-11/10/06	Pred Forte Refresh Plus
Todd Fladen 1330 Mercy Dr. NW, #312 Canton, OH 44708	Renewal of Agreement Contract No.: 0480033702 Expired: 10/05/2007	10/23/07-4/23/07	Pred Forte Refresh Plus
University Hospitals Ophthalmology 9000 Mentor Ave., #102 Mentor, OH 44060	Renewal of Agreement Contract No.: 0480041328 Expired: Not Listed	7/31/08-1/31/09	Pred Forte
University Ophthalmology Associates 1611 S. Green Rd., #306-C S. Euclid, OH 44121	New Kit Agreement Contract No.: New Expired: Not Listed	1/10/08-6/10/08	Pred Forte Acular LS

144. The physicians listed above (and many others not listed) were influenced by Allergan's free kits, and each of them prescribed Allergan's drugs as a result. The majority of these prescriptions were written for Government Program patients, mainly Medicare or Medicaid beneficiaries. These prescriptions caused false claims, tainted by Allergan's illegal kickbacks, to be submitted to Government Programs for reimbursement or payment, and subsequently to be reimbursed or paid for by these Government Programs. Indeed, the participation of doctors and pharmacists in the submission of false claims was not only foreseeable, it was the express intended consequence of Allergan's schemes.

145. Relator Wood has provided the Government with numerous CCK Agreements, along with Allergan's database that summarizes thousands of similar agreements that Allergan entered into with physicians throughout the United States, as well as detailed payment records Allergan maintained which closely tracked how kickbacks were influencing, and did influence, prescribing behavior. These records show the geographic region, payer, prescriber, and number of prescriptions written for both Allergan and competitor products. Some of these internal Allergan records are referred to as "Trinity reports."

146. Through CCK Agreements, Allergan provided individual ophthalmology practices with "free" samples that ranged in value from hundreds to thousands of dollars. Because of the significant cost of the CCKs, Allergan only provided them to physicians who agreed to prescribe a significant quantity of Allergan products in return. Allergan viewed the CCKs and included products as a "resource" to induce physicians to prescribe its drugs, and it sought to ensure that it received an adequate "return on investment." In keeping with that, health care professionals who prescribed primarily Alcon drugs and did not agree to switch to Allergan drugs, were not offered CCKs. For physicians already receiving CCKs, Allergan threatened to cease providing CCKs, and in many instances did cease providing CCKs, if they did not prescribe sufficient quantities of Allergan's drugs.

147. Sales representatives were themselves responsible for ensuring that CCK Agreements were only offered to physicians who would prescribe Allergan drugs in return; however, managers were responsible for approving representatives' decisions. Section V of the CCK Agreement requires signatures of the health care professional, sales representative, and Area Manager. In practice, sales representatives obtained verbal approval from the Area Manager and signed on his or her behalf.

148. Allergan taught Relator Wood, from his arrival at the Company, to leverage CCKs to successfully drive sales of Allergan products. Relator Wood was hired by Richard Morgan, who also served as Relator Wood's first Area Manager. (Morgan is now a consultant in Allergan's Eye Care Business Advisor Group.) During Relator Wood's interviews with Morgan in September of 2008, as well as during several field rides and phone conversations in late 2008, Morgan explained that CCKs were the critical tool to convince ophthalmologists to prescribe Zymar® and Acular LS®, and that the CCKs needed to be strategically leveraged in order to do so. Indeed, under Morgan's direction, the Ohio team had the highest number of CCK Agreements of any sales area in the country.

149. Field Training Manager William Scruggs taught Relator Wood the same lesson — i.e., the importance of strategically leveraging CCKs to drive sales — immediately following Relator's arrival at Allergan. In an email on November 26, 2008, Scruggs sent Relator Wood an Excel spreadsheet titled "CCK – Game Plan II" as a sample of effective use of CCKs. This "Game Plan" explicitly compared the quantity of CCKs and samples provided to a physician relative to the prescriptions of Allergan products written. The spreadsheet recorded the absolute quantity of CCKs and samples provided as well as prescriptions of Acular® and Zymar® written, and it also calculated a "Ratio" comparing kits and drugs provided versus prescriptions written. This "Ratio" was defined as "Script Total" divided by "CCK Totals." Ratios less than approximately 70% were highlighted in red, while those in excess of this value were black.

150. The comments in Scruggs' spreadsheet, which are included under the heading "Background / Action Plan," make even more explicit that Allergan intended to (and did) leverage CCKs, samples, and other products to induce physicians to prescribe its drugs. The

following are examples of script-to-kit "Ratios" listed in the spreadsheet as well as the accompanying "Action Plan":

- Community Eye Center, suburban Detroit, Michigan, had received 96 kits and written 23 prescriptions for a 24% ratio. The Action Plan noted that this clinic treated a number of Medicaid patients and that Allergan would "put [a] stop" to "giving away too many free meds." Another scorecard for a separate time period, included in the same spreadsheet, showed that they had received 144 kits and written 26 prescriptions for an 18% ratio. The Action Plan stated, "No more kits till we see a better return."
- Fahim Ibriham, an ophthalmologist from Port Huron, Michigan, had received one free kit and written 37 Allergan prescriptions for a 3700% ratio. The Action Plan stated, "[h]e claims he['s] 100% Allergan. Shut him down if [he] do[e]sn['t measure up ASAP."
- Great Lakes Ophthalmology, Michigan had received 480 kits and written 50 Allergan prescriptions for a 10% ratio. The Action Plan stated, "[h]ad talk about Zymar meds only. He [told] me he likes to give a bottle with script. Also uses 2 kits per pat[ient]. I explained the situation and he instructed his staff to write 2 scripts per patient to cover the kits. Goal: ratio is horrible. Go in preceptorship with him. Find out what['s really going on."
- Grosin, Spige, & Grey, Michigan, had received 840 kits and written 482 Allergan prescriptions for a 57% ratio. The Action Plan stated, "[t]oo much [kits and samples] going in. Need higher return. . . . [N]o more giving Acular away."

- Dr. Richard A. Kaiserman, East Tawas, Michigan had received 144 kits and written 52 Allergan prescriptions for a 57% ratio. The Action Plan stated, "25% goes to Medicaid. Not a beli[e]ver in NSAIDs. Gives 2 kits per pat[ients]. Goal kits talk about expense . . . can[']t support unless you['re] giving 1 kit per pat[ient]."
- Lake Lazer Eye Center, 35776 Harper Avenue, Charter Township of Clinton, Michigan, had received 48 kits and written 5 Allergan prescriptions for a 121% ratio. The Action Plan stated, "[b]ags. They are going with Alcon [because] of bags [i.e., equivalent kits from Alcon]. No more orders [in] 2006, un[til] they agre[e] to use us."
- Michigan Glaucoma Specialists, Royal Oak, Michigan had received 186 kits and written 116 Allergan prescriptions for a 62% ratio. The Action Plan stated, "[h]ad talk with them."
- Northern Eye Ophthalmology, Alpena, Michigan had received 432 kits, and written 123 Allergan scripts, a 28% ratio. The Action Plan states: "Recently 1 cat[aract surgery] kit per pat[ient], cut back on cat[aract surgeries]. Need 10ml Pred for 2nd eye. Goal: Watch TSS [total prescriptions] and JG Pads [pre-printed prescription pads], monitor 1-1 ratio."
- Rohr Eye & Laser, Grand Blanc, Michigan, had received 396 kits and written 250 Allergan prescriptions for a 63% ratio. The Action Plan stated, "[n]eed better ratio. Look at year[']s numbers to see if match[e]s up with kits. Huge account can[']t lo[]se, but not to be taken advantage of. . . ."

- Wilkinson Eye Center, Pontiac, Michigan, had received 528 kits and written 132 Allergan prescriptions for a 25% ratio. The Action Plan stated, "POOR Ratio, may cut Wilkinson…high Medicaid pop[ulation]. Leave lots of 5mls for Sharron coord. Into ECBA/Botox..happy with service."

151. The preceding comments from the spreadsheet that Field Training Manager Scruggs sent Relator Wood were indicative of Allergan's use of CCKs and product samples to induce physicians to prescribe Allergan products. The only way in which Scruggs' comments were perhaps unusual was in their explicitness: while both sales representatives and their managers made these same calculations and decisions continually throughout Relator Wood's employment at Allergan, they were generally only discussed in person or on the phone (i.e., not in writing), or using less direct language.

152. As a result of growing concern about the illegality of its use of CCKs, in late 2008, Allergan announced to its sales force via conference calls that it was terminating its provision of CCKs, citing its concern that the kits could be viewed as an inducement to physicians to use Allergan products. In a PowerPoint presentation, dated November 13, 2008, Allergan informed its External Disease sales force that CCKs would no longer be available and that free drug samples would only be available for the top 1,000 accounts through "Direct Sample Ship" agreements. (Allergan quickly dropped the 1,000-account limit due to push back from sales representatives.) The rationale for the revocation of the kits was the change in the PhRMA and the AdvaMed Codes. According to the presentation, a "[p]hysician's acceptance of free kits can be interpreted as being in violation of Federal Anti-Kickback statutes."

153. In response to physicians who complained about the cessation of free kits, sales representatives were instructed to inform them that "[v]iolations of the PhRMA [C]ode put the

physician, the representative and the company at risk. Any company in violation of these codes puts their customers at risk." Allergan subsequently established a free website where health care professionals can order kits (that do not include Allergan drugs) at a nominal cost. *See* http://www.allergancustomersupport.com/Assets/804133PCKCatalog.pdf (last visited Feb. 22, 2012).

154. Sales representatives themselves expressed widespread and considerable displeasure following the announcement of the termination of CCKs. They feared that without CCKs, Allergan would be placed at a competitive disadvantage relative to Alcon, which continued to induce physicians using analogous kits. Sales representatives' concern serves as a strong indication of both the centrality and effectiveness of CCKs in Allergan's overall kickback strategy.

155. Perhaps fearing too significant a decline in sales were it to cease providing kickbacks altogether, Allergan took two steps to reduce the impact of its decision to halt the CCK program. First, it provided high-prescribing physicians with massive final deliveries of CCKs, which in some instances contained quantities of CCKs sufficient to last six months. Second, Allergan continued using free product samples as inducements to physicians to prescribe its products. The following list of physicians had been receiving free CCKs prior to their discontinuation in December 2008. At that time, Allergan decided that it would continue to provide Pred Forte® and other Allergan drug products to these physicians via mail, so long as they continued to prescribe its drug products in sufficient quantity.

Ophthalmologist/Clinic Name	Address	City	Contract No.
Eye Centers of Ohio	800 McKinley Ave	Canton, OH	480061104
Eye Centers of Ohio	Frank Road	Canton, OH	480061046

Roholt Vision	5890 Mayfair Rd.,	North Canton, OH	480059843
Martuccio Eye Care	302 Niles-Cortland Rd	Warren, OH	480055600
Sheik - Warren Ophthalmology	3921 E Market St	Warren, OH	480055614
Lasik Plus	6800 Rockside Rd #A	Independence, OH	480056404
Summit Ophthalmology	1 Park West	Akron, OH	480051211
Belmont Eye Clinic	3020 Belmont Ave	Youngstown, OH	480059431
Canton Ophthalmology	Tuscarawas Drive	Canton, OH	480061842
Cleveland Eye Clinic	2740 Carnegie Ave	Cleveland, OH	480059669
The Eye Center	314 Penco Road	Weirton, WV	480060758
Davis Eye Center	789 Graham Rd.,	Cuyahoga Falls, OH	480061298
Richard Lehrer, MD	985 Sawburg Ave	Alliance, OH	480059465
Clear Vision Centers	1155 State Rt. 303,	Streetsboro, OH	480054270
Premium Surgery Center	5319 Hoag Road,.	Elyria, OH	480060431
Elyria Surgery Center	Hoag Road	Elyria, OH	480060431

156. The Fraudulent Kickback Scheme described above constitutes a violation of the AKS, was made with the intent to induce, and did induce physicians to prescribe Allergan drug products that were reimbursed by Government Programs, through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729. Moreover, Allergan's kickbacks caused pharmacies submitting claims to the Government to falsely certify compliance with applicable laws and regulations, including that the claims were not tainted by illegal kickbacks.

C. Using Sample Shipment Agreements to Bribe Health Care Professionals

157. Having been pressured to terminate its use of CCKs as kickbacks, Allergan devised a substitute scheme to induce physicians to prescribe its drugs by providing them with large quantities of free product samples. Similar to the process by which they had ordered CCKs,

physicians coordinated with an Allergan sales representative to submit a "Sample Shipment Agreement" through which they ordered a large, six-month supply of free product samples.

158. The "Sample Shipment Agreement" consisted of a one page form, distributed by Allergan to its sales representatives, including to Relator Wood, for the purpose of providing free drug samples to ophthalmologists. These forms, which were periodically updated, included print that identified the document (e.g., "APG 4118 REV. 7/09 MDR APC44A109") on the bottom left-hand portion and the Allergan marketing department facsimile number ("MARKETING FAX (866) 257-0281") on the bottom right-hand portion.

159. In Section II of the Sample Shipment Agreement, ophthalmologists were able to choose from seven listed Allergan drugs, including Acuvail®, Pred Forte®, Optive®, Optive Sensitive® and Refresh Liquigel®. They could also fill in an "Other" request for an unlisted drug, such as Zymar®. Section III of the agreement allowed the Practitioner to choose the "MONTHLY FORECAST" and "MAXIMUM 6 MONTH QUANTITY." The Allergan sales representative generally worked with the surgical counselor or coordinator to estimate the supply of drugs required, which was based on the monthly surgical volume for the entire clinic.

160. The Sample Shipment Agreements did not reference the cost of the provided drugs.

161. The samples were shipped from Allergan's fulfillment facility in Waco, Texas, by its subsidiary Allergan Sales LLC, located at 8301 Mars Drive, Waco, Texas 76712. Shipping costs were always paid by Allergan.

162. The follow are examples of Sample Shipment Agreements that Allergan used to induce physicians to prescribe its drug products:

Name & Address of Physician or Practice	Contract No. & Expiration Date	Effective Dates of the Agreement	Free Drugs Provided in Kits	Initial Ship Quantity
Belmont Eye Clinic 3020 Belmont Ave. Youngstown, OH 44505	Renewal of Agreement Contract No.: 0480065304 Expires: Not Listed	08/06/09- 02/06/10	Acuvail Pred Forte Optive Optive Sensitive	168
Canton Ophthalmology 2600 Tuscarawas St., W Suite 200 Canton, OH 44708	Renewal of Agreement Contract No.: "Replace Existing Contract" Expires: Not Listed	11/03/09- 05/03/10	Acuvail Pred Forte Optive Refresh Liquigel	348
Canton Ophthalmology 2600 Tuscarawas St., W Suite 200 Canton, OH 44708	New Agreement Contract No.: 0480066438 Expires: Not Listed	09/22/09- 02/22/10	Acuvail Pred Forte Optive	204
Clearchoice Laser 7001 S. Edgerton Rd. Brecksville, OH 44141	Renewal of Agreement Contract No.: 0480064174 Expires: 08/10/2009	07/10/09- 01/10/10	Pred Forte Optive Sensitive	144
Cleveland Eye Clinic 2740 Carnegie Ave. Cleveland, OH 44115	Renewal of Agreement Contract No.: 0480064582 Expires: Not Listed	08/13/09- 02/13/10	Acuvail Pred Forte Optive	216
Eye Centers of Ohio 800 McKinley Ave., NW Canton, OH 44703	Renewal of Agreement Contract No.: 0480064607 Expires: Not Listed	08/13/09- 02/13/10	Acuvail Pred Forte Optive Zymar	144
Eye Centers of Ohio 6407 Frank Rd. North Canton, OH 44720	Renewal of Agreement Contract No.: 0480064646 Expires: Not Listed	08/13/09- 02/13/10	Acuvail Pred Forte Optive Zymar	108
Ohio Eye Alliance 985 Sawburg Alliance, OH 44601	New Agreement Contract No.: Not Listed Expires: Not Listed	10/22/09- 04/22/10	Pred Forte	144
Ohio Eye Alliance 985 Sawburg Alliance, OH 44601	Renewal of Agreement Contract No.: 0480064159 Expires: Not Listed	08/11/09- 02/11/10	Acuvail Pred Forte Optive	108
Ohio Eye Association 8110 Market St. Youngstown, OH 44512	Renewal of Agreement Contract No.: 0480064592 Expires: Not Listed	08/06/09- 02/06/10	Acuvail Pred Forte Optive Zymar	204
Ophthalmic Physicians, Inc. 9485 Mentor Ave., #110 Mentor, OH 44060	New Agreement Contract No.: 0480068575 Expires: Not Listed	09/30/09- 03/30/10	Acuvail Pred Forte Optive	120
Roholt Vision Institute 5890 Mayfair North Canton, OH 44720	Renewal of Agreement Contract No.: 0480064861 Expires: Not Listed	08/11/09- 02/11/10	Acuvail Pred Forte Optive Optive Sensitive	108
The Eye Center 314 Penco Rd. Weirton, WV 26062	Renewal of Agreement Contract No.: 0480065701 Expires: Not Listed	08/06/09- 02/06/10	Acuvail Pred Forte Optive Zymar	108

163. Relator Wood has provided the Government with hundreds of Sample Shipment Agreements along with a database of thousands of similar agreements entered into throughout the United States between Allergan and health care professionals.

164. The samples provided under these agreements were of significant value. Because of the large six-month supplies provided under the agreements, they were frequently valued in the thousands of dollars. Just as under its CCK scheme, Allergan recognized the significant cost of fulfilling Sample Shipment Agreements, and as such, only did so for those physicians who agreed to prescribe significant quantities of its drugs in return. The Sample Shipment Agreements were therefore a blatant quid pro quo. Allergan only offered Sample Shipment Agreements to physicians who already prescribed or agreed to prescribe its products. Agreements were not offered to physicians who prescribed primarily Alcon products such as Vigamox® or Nevanac®. For physicians with existing agreements who did not prescribe its products in sufficient quantity or switched to a competitor's products, Allergan threatened to revoke or did cease fulfillment of their Sample Shipment Agreements.

165. Sample Shipment Agreements took the place of CCKs as the centerpiece of Allergan's marketing campaign for Acular LS® and Zymar®, and later for Acuvail®. Recognizing the effectiveness of Sample Shipment Agreements as an inducement, Area Manager Jon Weidner instructed Relator Wood to sign up as many physicians as possible — contingent, of course, on those physicians' agreement to prescribe Allergan products.

166. Just as they had previously done with regard to CCKs, sales representatives and their managers continued to monitor the quantity of free samples provided to these physicians relative to the quantity of Allergan products that they prescribed. In an email sent to his district

on April 24, 2009, Area Manager Jon Weidner instructed sales representatives to "[m]onitor samples of Acular on MOOSS" (Allergan's online sample management program) and "make sure we are not leaving more than what we are getting [prescribed]." With regard to Zymar®, Weidner told sales representatives: "Do not over-sample/monitor samples on MOOSS/RX's." He also instructed them, under the heading of "Zymar," to "[a]dd value to Pred-Forte." That instruction apparently corresponds with Weidner's direction with regard to Acular LS®, in this same email, to "[l]everage Pred-Forte!!!!!!!!!!" *See supra* ¶ 127.

167. Beyond providing general advice, Weidner and other Area Managers played an active role in ensuring that their sales representatives achieved a sufficient return on investment on free samples provided to physicians. Sample Shipment Agreements required not only the signatures of the health care professional and sales representative but also that of the Area Manager. Just as was the case with CCK Agreements, sales representatives usually obtained verbal approval from Area Managers and then signed on their behalf. Relator Wood understood that Weidner would not grant approval to Sample Shipment Agreements for physicians who did not prescribe a significant quantity of Allergan products.

168. Kim Johnson, the Senior Territory Manager in Relator Wood's territory, recurrently provided similar instruction to strategically utilize drug samples as inducements. In an email to Relator Wood on April 5, 2009, which Johnson sent in response to a shipment notice of 100 bottles each of Pred Forte® and Acular LS® to Ohio Eye Associates, Johnson wrote,

> We may want to confirm the need for Acular LS with Kelly at Dr. Oh's office. Also, we shipped them 244 Pred Forte for April. Probably that is all they need for the next 3-4 months. We may need to leverage the Pred down the road and we don't want them to stock pile it so we have nothing to negotiate.

(emphasis added).

169. In another email to Relator Wood on April 5, 2009, this one in response to a shipment notice of 120 bottles of Pred Forte® to Dr. Martin Markowitz, Johnson asked Relator Wood,

> Have we confirmed this number with this office. I thought I remembered their numbers to be much lower – like 60. Possibly they have picked up, but we don't want to send in too much either until we get a true commitment to keep using Zymar/Acular.

(emphasis added).

170. In a final email sent to Relator Wood by Johnson on April 5, 2009, in response to a shipment notice of 250 bottles each of Pred Forte®, Zymar®, and Acular LS®, which were shipped to The Eye Center, Johnson wrote, "[w]e need to discuss the 250 Zymar and Acular. I don't think this is something we want to ship to them because we will just lose prescriptions."

171. Both Weidner and Johnson's instructions to leverage mail-order samples as inducements were not exceptional; rather, they were indicative of Allergan's systematic use of Sample Shipment Agreements, just as it had used CCKs, to induce physicians to prescribe its drug products.

172. Because provision of free samples was contingent on physicians' agreement to prescribe Allergan products, Allergan only offered Sample Shipment Agreements to those who prescribed its drugs. For example, physicians at Eye Care Associates in Youngstown, Ohio (Drs. John Aey, Hai-Shuh Wang, Lyn Yakubov, Keith Wilson, Sergul Erzurum, Robert Gerberry, Richard Wyzynski) had a long history of prescribing Alcon products and using Alcon surgical equipment. They were therefore not offered free samples of Allergan drugs under a Sample Shipment Agreement. In May 2010, the practice agreed to begin prescribing Zymar®, at which point Allergan offered it a Sample Shipment Agreement. Dr. Aey signed two agreements, one for

each of the practice's clinic locations, and began receiving large quantities of Pred Forte®, Zymar®/Zymaxid®, Acuvail®, Optive®, and FML® beginning in June 2010.

173. Likewise, Allergan ceased providing samples to physicians who failed to prescribe its products in sufficient quantities:

- Dr. Doug Ripkin, Clear Vision Centers, 1155 State Route 303, Streetsboro, Ohio 44241. After Dr. Ripkin switched, in March 2009, from prescribing entirely Zymar® to splitting his anti-infective prescriptions half-and-half between Vigamox® and Zymar®, Allergan reduced his shipments of Pred Forte® accordingly;
- Dr. Bruce Jacobson, Ophthalmology Consultants, Inc., 36100 Euclid Avenue Suite 450, Willoughby, Ohio 44094. After Dr. Jacobson began prescribing Vigamox® and receiving Alcon patient care kits in April 2009, his Allergan samples were terminated;
- Cleveland Eye Clinic, 7001 S. Edgerton Rd., Suite B, Brecksville, Ohio 44141. In January 2010, the clinic began to prescribe Xibrom® instead of Acular LS®/Acuvail®, at which point Allergan stopped providing it with Pred Forte® for its cataract surgeries. (They were already prescribing Vigamox®.)
- Drs. Laurence Karns, Gregory Gray, Jerry Macher of Eye Centers of Ohio, 6407 Frank Avenue NW North Canton, Ohio 44720, all switched to Alcon products in February 2010, while Dr. Paul Turgeon continued to use Allergan products. As a result, Allergan significantly decreased the quantity of Pred Forte® shipped to Eye Center of Ohio to a quantity only sufficient to cover Dr. Turgeon's surgeries; and

- Dr. James Martuccio, Warren Eye Clinic, Inc., 302 Niles Cortland Road North East, Warren, Ohio 44484. In April 2010, Allergan ceased to provide Pred Forte® after Dr. Martuccio began prescribing Alcon's Nevanac® and Vigamox®. Allergan continued provide free samples of Acuvail® in an attempt to induce him to return to Allergan products.

174. In June 2010, Allergan announced that it would cease providing free product samples to physicians due to liability concerns similar to those that had influenced it to cease providing CCKs eighteen months before. Dave LeCause, Allergan's Vice President of US Eye Care, announced the change on a conference call with the entire sales force on June 18, 2010. LeCause informed the sales force that the company needed to "change the way we do business so Allergan is not giving the appearance of engaging in any quid pro quo." "Things in the industry," LeCause said, "are not like they used to be." Allergan is "operating in a heightened state of awareness." LeCause, as a twenty-year veteran of Allergan, was very familiar with the Company's Fraudulent Kickback Scheme. His comments that Allergan's sampling scheme created the "appearance" of a quid pro quo apparently stemmed from his understanding that, in this case at least, appearance mirrored reality.

175. During a sales meeting on June 22, 2010, Allergan again announced to its sales force that the Company would cease providing free drug samples. It also informed sales representatives that anyone who put such a quid pro quo offer in writing (in a so-called "homemade" sales tool) would be terminated. The sin, of course, was to have expressed the inducement in writing, not to have had actually provided it, as Allergan had taught all its ophthalmology sales representatives to do exactly this for years.

176. As was the situation when Allergan terminated the CCK program, sales representatives again expressed displeasure at the termination of the sampling program. Both sales representatives' response to the discontinuation of the sampling program, as well as management's explanation of that discontinuation, serve to emphasize the central and illicit role it played in driving sales of Acular®, Acular LS®, Acuvail®, Zymar®, and even Restasis®.

177. During a "breakout session" with Area Manager Jon Weidner and sales representatives from Relator Wood's district, held on June 22, 2010, immediately following the announcement of the discontinuation, Weidner and sales representatives discussed their expectation that no longer providing physicians with samples would result in a significant decline of Acuvail® and Zymaxid® prescriptions. Specifically referring to the expected decline in Acuvail® and Zymaxid® prescriptions, Weidner stated, "That's going to happen." He described the "surgical portfolio," i.e., Acuvail® and Zymaxid®, as a "big concern," and asked sales representatives, "How many of those [accounts receiving Pred Forte®] is it really going to make a huge, like a huge deal?" Sales representative Farley Dillinger responded, "All of them," and sales representative Ali Grumet responded, "I mean they're all going to be pissed."

178. Relator Wood's district expected many of these physicians, in the absence of Allergan's kickbacks, would begin prescribing cheaper, generic alternatives to Acuvail® and Zymaxid®. Kate Bergan asked the group whether they believed that doctors would react by saying, "Well, I'm just, we're just going to use generics. We're just going to write all generics." Bergan continued, "I feel like we're getting, we're going to hear that, right?" Grumet and Phil Edmondson as well as a number of other sales representatives answered, "Yes," expressing the group's consensus. The conversation later continued:

Bergan: But don't you think it's going to be easier [for

	physicians] to continue to write [soon-to-be generic] Zymar®?
Edmondson:	They'll say, I'm not going to upgrade to something that's more expensive.
Unidentified speaker:	Or I'm not going to [cut off by next speaker]
Unidentified speaker:	They won't get samples.
Weidner:	They're not going to get resources from us and that's the [cut off by next speaker]
Grumet:	I think the bigger resource was the Pred Forte®.
Relator Wood:	But what about printing [patient instruction sheets]? Will we print?
Weidner:	There is going to be [sic] accounts that we are going to lose from this. There is no doubt that [cut off by next speaker]

179. The effectiveness of Allergan's kickbacks was so substantial that those in Relator's district expected that their discontinuation would not only impact physicians' willingness to prescribe Acuvail® and Zymaxid®, which were the primary targets of the kickbacks, but would also have a "ripple effect" or "domino effect" that would impact prescriptions of Restasis® as well. Weidner actually referred to the expected decline in Restasis® prescriptions as a "bigger deal" than the one expected in the surgical portfolio and asked sales representatives, "[W]ho is going to truly be pissed to the point that it's going to affect our Restasis® conversions and business for a while?" Bergan responded, "Most of them." At another point Bergan stated that physicians are "not going to want to do us any favors. They're

going to go through the same stages of anger and frustration that we did. … I feel like it's our Restasis® conversation will either be completely not heard or [inaudible]."

180. Effectively summarizing the expected impact, Weidner commented, "I mean, I wanted to start heavily drinking when I was on the conference call" during which the decision to discontinue bulk provision of free drugs was announced. "I mean, literally."

181. While it clearly followed from the anticipated decline in Acuvail®, Zymaxid®, and Restasis® prescriptions that Allergan's mass provision of free drugs functioned as a kickback, Weidner and sales representatives discussed even more explicitly that Allergan's provision of drugs was, and had long been, a quid pro quo. Weidner stated,

> There are no longer, they [Allergan managers] no longer want us nor should we be doing any kind of quid pro quo type of stuff, or you know, going after Alcon saying, we'll give you a Pred [Forte®] for this one. There's not, the days are gone where we can like provide 100% of Pred [Forte®] for an account

(emphasis added). Bergan described Allergan's long-standing provision of CCKs and free drugs as a "monster": "I mean, this monster was created a long time before any of us got here, and it's been bit by bit chipped away," referring to the discontinuation of CCKs, "and now this is the final blow." Maria Zanardo responded, "Right, for all of us that have been around for a while, this was the way, the law of the land."

182. The Fraudulent Kickback Scheme described above constitutes violations of the AKS, made with the intent to induce physicians to prescribe Allergan drug products that were reimbursed by Government Programs, through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729. Moreover, Allergan's kickbacks caused pharmacies submitting claims to the Government to falsely certify compliance with applicable laws and regulations, including that the claims were not tainted by illegal kickbacks.

D. Bribing and Rewarding High Prescribers

183. As described in the preceding sections, Allergan provided CCKs and Sample Shipment Agreements to a large number of physicians in order to induce them to prescribe its drugs. However, for a small subset of the highest-prescribing cataract surgeons, Allergan offered additional, "special" inducements to prescribe its drugs. Allergan provided these high-prescribing cataract surgeons with substantial volumes of free drugs, including trade-size bottles of Acular LS® and Zymar®, which were frequently valued at hundreds of thousands of dollars per year.

1. Eye Centers of Ohio

184. Dr. Paul Turgeon is the lead surgeon for Eye Centers of Ohio of Canton, Ohio, which is one of the country's largest cataract surgery centers, performing between 200 and 250 cataract surgeries per month. Approximately 75% of the cataract surgeries performed by Eye Centers of Ohio are performed on patients covered by Medicare or Medicaid.

185. Dr. Turgeon routinely prescribed both a topical anti-infective and topical NSAID in conjunction with cataract surgery, and he was aware of the value of his business to Allergan and Alcon. Lacking a strong clinical preference for either Allergan or Alcon drugs, Dr. Turgeon routinely threatened to switch to Alcon products and prescribe Vigamox® and Nevanac® instead of Zymar® and Acular LS®, if Allergan was unwilling to provide his practice with more lucrative concessions in exchange for prescribing its drugs.

186. Around 2007, in order to induce Dr. Turgeon and Eye Centers of Ohio to continue prescribing Allergan products rather than switch to prescribing Alcon products, Allergan agreed to provide Eye Centers of Ohio with copious free, "trade-size" samples of Acular LS® to provide to all its cataract patients. "Trade-size" samples are larger than usual free product

samples, in this case 5 ml instead of the standard 1 ml. The 5 ml bottle was the same size as a standard prescription of Acular LS® and sufficient for an entire course of therapy. The provision of trade-size bottles, particularly in the quantity that Allergan provided them to Eye Centers of Ohio, was a special concession that was not offered to smaller customers, and was only provided to Eye Centers of Ohio out of fear of entirely losing its business to Alcon. In exchange for receipt of these trade-size samples, Dr. Turgeon and his colleagues prescribed Zymar® in conjunction with each cataract surgery.

187. A 5 ml bottle of Acular LS® has a retail cost of between $70 and $100, and Allergan provided a bottle for use with each surgery performed at Eye Centers of Ohio. Allergan therefore provided Eye Centers of Ohio with Acular LS® valued between $180,000 (200 surgeries/month x $70) and $300,000 (250 surgeries/month x $100) annually.

188. Recognizing the heavy cost of its inducement to Eye Centers of Ohio, in 2008 Allergan sought to stop providing Eye Centers of Ohio with free trade-size bottles of Acular LS®. However, when told that Allergan planned to cease this special concession, Eye Centers of Ohio threatened to stop prescribing Allergan drugs and switch to a competitor. In order to prevent Eye Centers of Ohio from doing so, Allergan sales representative Kim Johnson obtained special approval from Allergan management to continue providing the practice with substantial quantities of free trade-size samples. This continuance was directly approved by External Disease Marketing Director for Acular LS®, Mary Ellen Esgro. That Allergan wished to stop providing these trade-size samples, and only continued to do so after being threatened, clearly demonstrates that the trade-size samples were an inducement, only provided contingent on Eye Centers of Ohio's agreement to prescribe Zymar®.

189. When Allergan launched Acuvail® in September 2009 in anticipation of generic availability of Acular LS®, it reached a similar agreement with Dr. Turgeon and Eye Centers of Ohio to continue receiving free trade-size samples of one Allergan product in exchange for their agreement to prescribe another. In place of Acular LS®, Allergan began providing Eye Centers of Ohio with free trade-size samples of Zymar® (5 ml) and Pred Forte® (10 ml), as well as standard, non-trade-size samples of Acuvail® for use in conjunction with each cataract surgery. In exchange for Allergan's provision of these free product samples, Dr. Turgeon and other Eye Centers of Ohio surgeons prescribed Acuvail® in conjunction with each cataract surgery.

190. Allergan similarly provided "special" inducements of trade-size samples of Acular LS®, and later Zymar®, to approximately ten to twenty large cataract surgery centers throughout the country.

191. In addition to free trade-size samples of Acular LS® and Zymar®, Eye Centers of Ohio also received free Custom Care Kits (prior to December 2008), free Pred Forte®, free patient instruction sheets, and free prescription pads, all of which were provided in exchange for its agreement to continue prescribing Allergan drugs.

2. Ohio Eye Alliance

192. In early 2010, Allergan provided a similar "special" inducement to Dr. Richard Lehrer in order to prevent him from switching to a competitor's products. Dr. Lehrer is an ophthalmologist at Ohio Eye Alliance, 985 S. Sawburg Ave, Alliance, Ohio. At the time, he split his NSAID prescriptions between Acuvail® and Xibrom® and his anti-infective prescriptions between Zymar® and Vigamox®, writing half his prescriptions for Allergan products and a fourth each for Alcon and ISTA products.

193. After trying Acuvail® for several months, in February 2010, Dr. Lehrer and his surgical coordinator, Jan Hobson, as well as his optometrist intern, Dr. Liana Allabadi, informed Relator Wood that Dr. Lehrer was disappointed with the efficacy of Acuvail® relative to Acular LS®. Dr. Lehrer believed that Acuvail® did not suppress inflammation as well as Acular LS® did. In an attempt to find a regimen of Acuvail® that he believed was as effective as Acular LS®, Dr. Lehrer began prescribing Acuvail® at an increased post-operative dose of three times daily. Dr. Lehrer, however, remained unsatisfied with the results.

194. In response to Dr. Lehrer's dissatisfaction, and in an attempt to resolve his concerns, Allergan's Director of External Disease Monie Hussain personally met with Dr. Lehrer at a meeting of the American Society of Cataract and Refractive Surgery, which was held in Boston on April 9 through 14, 2010. Following the meeting, Hussain recommended that Dr. Lehrer speak with Allergan's Medical Director for Acuvail®, Dr. David Hollander, who Hussain hoped would be able to address Dr. Lehrer's concerns. Dr. Lehrer spoke to Dr. Hollander via phone; however, his clinical concerns persisted. Nonetheless, Dr. Lehrer continued to prescribe Acuvail® at a dose of three-to-four times per day in conjunction with approximately half his cataract surgeries.

195. After hearing of Dr. Lehrer's continued concerns, Hussain offered Dr. Lehrer 216 5 ml trade-size bottles of Acular LS®, in order to engender good will to induce him to continue prescribing Zymar®, and hopefully, eventually, to prescribe Acuvail®. Hussain calculated that that quantity of Acular LS® would be sufficient to last Dr. Lehrer for three months of cataract surgeries. As of July 1, 2010, Dr. Lehrer had received 72 of the 216 bottles, enough for the month of June.

196. Hussain provided Dr. Lehrer with these trade-size bottles of Acular LS® in an attempt to induce Dr. Lehrer to continue prescribing Allergan products. On information and belief, Hussain's attempt was successful, and Dr. Lehrer continued to prescribe Zymar®. After Relator Wood provided the trade-size Acular LS® bottles to Dr. Lehrer, Area Manager Jon Weidner complimented Relator Wood for "leveraging samples appropriately," and for his effective use of "cross-functional relationships within the organization" to obtain Hussain's assistance in the matter.

197. Allergan's use of CCKs and Sample Shipment Agreements to induce physicians to prescribe its brand-name drugs instead of generic alternatives was effective, as indicated by the significant discrepancy in prescribing habits between physicians who were the recipients of these inducements and those who were not. The Cleveland Clinic of Cleveland, Ohio, for example, performs cataract surgeries but does not accept free samples. It utilizes largely generic anti-infective and non-steroidal drugs in connection with its cataract surgeries. The Cleveland Clinic's use of generic anti-infective and non-steroidal drugs significantly lowers the cost of drugs prescribed in conjunction with its cataract surgeries, thereby saving Government Programs significant sums. While a number of factors drive physicians' choice of medication, the significant disjunction between the habits of physicians at one of the nation's leading medical centers and those to whom Allergan leverages its CCKs and product samples, is nonetheless suggestive of the substantial influence of Allergan's illicit promotional efforts, as well as the significant cost incurred by Government Programs as a result.

E. Allergan Provides Additional Inducements, Including Pre-Printed Prescription Pads, Patient Instruction Sheets, and Contributions to Physicians' Favored Charities, to Induce Physicians to Prescribe Its Drug Products

198. Although Allergan has ceased providing physicians with kickbacks of Custom Care Kits and drug samples, the Company continues to provide other inducements to physicians to prescribe its drugs. These ongoing inducements include free customized patient instruction sheets; free customized prescription pads, with pre-printed prescriptions for Allergan drugs; and contributions to physicians' favored charities.

199. In conjunction with their cataract surgeries, most ophthalmologists provide patients with an instruction sheet that outlines the pre- and post-operative drug regimens, and provides other miscellaneous direction, e.g., not to eat on the night prior to surgery. These patient instruction sheets are almost always customized so that they contain the individual physician or clinic's preferred prescribing regimen, as well as the physician or clinic's name and/or logo. In addition, the sheets are generally printed in color, on glossy paper, making them relatively expensive. Despite the expense, ophthalmologists generally regard them as a necessity.

200. Allergan assisted physicians to design and provided them with these patient instruction sheets, in exchange for physicians' agreement to prescribe its drugs. Prior to December 2008, an Allergan sales representative worked with a customer to design a customized instruction sheet template. Once the template was finalized, the Allergan sales representative then submitted an order for printing through JG Pads, 759 S. Broadway, Akron, OH 44311, and the finished instruction sheets were shipped to the ophthalmologist. Ophthalmology practices typically received 1,000 patient instruction sheets per shipment. Allergan paid for the costs of both printing and shipping the instruction sheets.

201. In December 2008, in response to revisions to the PhRMA and ADVAMED guidelines, Allergan announced that sales representatives would no long be allowed to assist physicians in the creation of Patient Instruction Sheets. Physicians, however, could still design and order the instruction sheets themselves through the JG Pads website. As the PowerPoint presentation announcing the change to sales representatives stated, "Allergan will pay for a subscription to this site on behalf of our customers," and "[t]here will be no cost to customer[s] for this service."

202. Allergan also provided physicians who prescribed its products with free, customized, pre-printed prescription pads. Sales representatives assisted physicians to order the pads, usually by faxing an order form to Allergan. The pads were pre-printed with the physician's name, as well as Allergan drug products. In some instance, the pads were also pre-printed with instructions to use Zymar® or Acular LS® off-label, e.g., "use _ days prior to surgery" or "use _ days after surgery."

203. For example, the "Fax Order" form for the Cleveland Eye Clinic included an order for pads pre-printed with the clinic's logo, address, physician names, and prescriptions for Acuvail®. The order was for 20 pads of 50 pages each, or 1,000 Acuvail® prescriptions.

204. The prescription pads are printed by JG Pads, the same company that prints the patient instruction sheets. Allergan pays all costs associated with the pads, including shipping. According to the JG Pads website, a standard order of 20 pads currently costs $53. Pads with special security features are more expensive and can cost as much as $150.

205. Allergan used patient instruction sheets and pre-printed prescription pads to induce physicians to prescribe its drugs. It only provided patient instruction sheets and pre-printed prescription pads to physicians who prescribed its drugs in significant quantities.

Physicians who prescribed largely Vigamox® and Nevanac® were not offered free patient instruction sheets or pre-printed prescription pads, and Allergan revoked its provision of the sheets and pads from physicians who had initially prescribed its products but subsequently switched to a competitor's. Just as with CCKs and Sample Shipment Agreements, managers instructed sales representatives that both patient instruction sheets and pre-printed prescription pads were tools to drive sales.

206. Ophthalmologists and ophthalmology practices in Relator Wood's territory to which Allergan provided free patient instruction sheets and pre-printed prescription pads included: Drs. Jamie Zucker, Jeffrey Congeni, and Barbara Barchiesi of Canton Ophthalmology Associates, Canton, Ohio; Dr. Gregory Eippert of Ophthalmic Physicians Incorporated, Mentor, Ohio; Drs. Andrew Pederzolli and Bart Brine of Brine and Pederzolli, Alliance, Ohio; Ophthalmology Consultants, Inc. of Willoughby, Ohio; and Ohio Eye Alliance, Inc. of Alliance, Ohio. All of these ophthalmologists and ophthalmology practices treated Medicare and/or Medicaid patients, and as a result of Allergan's provision of kickbacks, prescribed Allergan drugs that were reimbursed by Government Programs.

207. During the "breakout session" following Allergan's announcement that it would no longer provide physicians with large quantities of free drug products, Area Manager Jon Weidner described to sales representatives how, lacking Pred Forte® to use as kickbacks, they should continue to leverage "printing" (i.e., patient instruction sheets and pre-printed prescription pads) as kickbacks. Instructing sales representatives how to respond to a hypothetical physician planning to begin prescribing generics to instead continue prescribing Allergan's products, Weidner stated:

> You know, you kind of gotta like [tell physicians], it's your decision, but I would hope that you would look at the resources that we can provide, from Zymaxid® rebates, printing. You don't want to go quid pro quo, but there's a lot of support that we can still give you.

Despite Weidner's insistence that providing valuable "resources" and "support" in exchange for physicians' agreement to prescribe Allergan products does not constitute a "quid pro quo," the substance of this scenario clearly remains, nonetheless, a quid pro quo.

208. In addition to providing physicians with free instruction sheets and pre-printed prescription pads, Allergan makes donations to physicians' favorite charities in exchange for those physicians' agreement to prescribe its drug products. A spreadsheet sent to Relator by Training Manager Bill Scruggs on November 26, 2008, shortly after Relator joined Allergan, included a note that Allergan agreed, after meeting with Senior Vice President Joseph Schultz, to give $10,000 to the favorite charity of Michigan ophthalmology clinic Anderson Eye to induce Anderson Eye to prescribe Allergan's drug products. Allergan has routinely leveraged similar donations to favored charities to induce physicians to prescribe its drugs. Doing so is in violation of the Anti-Kickback Statute and HHS OIG guidance, which describes "contributions determined in any manner that takes into account past or expected prescriptions, orders, or purchases of items or services payable by any Federal health care program" as a violation. *See* U.S. Department of Health and Human Services, Office of Inspector General Advisory Opinion No. 08-02 (issued Jan. 29, 2008).

F. Allergan Provided Free and Below-Market-Rate Consulting Services to Induce Ophthalmologists to Prescribe Restasis® and Other Drug Products

209. Through its Eye Care Business Advisory Group ("ECBA"), as well as in select instances through an external partner, Allergan has provided ophthalmologists and optometrists

with free or below-market-rate consulting services as an inducement to prescribe its drugs. These included Acular LS®, Acuvail®, Zymar®, and Zymaxid®; however, Restasis® was the primary focus of this component of Allergan's kickback strategy, and the Company made free provision of consulting services a centerpiece of its campaign to increase sales of the drug. Allergan's purpose in providing these services was twofold: (1) to induce physicians to prescribe Allergan drugs in exchange for the valuable consulting services provided by Allergan; and (2) to assist physicians in constructing "dry eye practices," as part of which physicians would then prescribe large quantities of Restasis®.

1. Consulting Services Background

210. Allergan offers a menu of consulting services, which range in the degree of support that they provide to offices. The most basic of these is Allergan *Access*®, which Allergan describes as a "Web-based suite of practice management tools and resources" that "combines the very best programs developed jointly by Allergan and BSM [C]onsulting . . . ." BSM Consulting, 936 Southwood Blvd., Suite 102, Incline Village, Nevada 8945, Allergan's external partner, describes itself as providing management solutions to a wide variety of health care clients, including hospitals, physicians, health care personnel, and pharmaceutical and device manufacturers. With specific regard to health care providers, BSM aims to assist physicians in navigating the financial and operational challenges of their practices.

211. The Allergan *Access*® eLearning Center, just one of the many resources on the site, includes in excess of fifty continuing education programs specifically designed for ophthalmologists. Among these are the "Basics of Medical Practice Finance," "Fundamentals of Diagnosis Coding," "How to Attract (Unwanted) Attention from Medicare," "Documenting a Patient's Ocular History," and "Dry Eye Disease."

212. Two Allergan *Access*® Utilization Reports, dated November 30, 2008, and December 31, 2009, respectively, show that physicians in the Ohio area use the service regularly as a part of their practices. The mean number of visits to the site by "Level 2 Subscribers" was 36 in 2008 and 24 in 2009. In 2008, the most frequent user of the site was Tri-State Centers for Sight of Cincinnati, Ohio, which visited Allergan *Access*® 189 times during the first eleven months of the year. Eye Care Associates of Greater Cincinnati, Inc., Cincinnati, Ohio, visited Allergan *Access*® 155 times during 2008 and 72 times during 2009.

213. In addition to the online tools offered through Allergan *Access*®, the Company also provides individualized, in-person consulting services through its internal consulting division, Eye Care Business Associates ("ECBA"). Consultants working for ECBA are employed directly by Allergan and are known as "business advisors." As detailed in a handout provided to sales representatives, ECBA provides a broad range of services, including online practice management tools and resources; educational seminars; and in-person training for staff, administrators, and management. Its training programs aim to help physicians' staff "maximize its potential through a variety of training and development tools that focus on leadership and communication issues, telephone skills, patient counseling, management of the accounts receivable process, job descriptions and work performance review, and much more."

214. As described in greater detail below, while Allergan offered subscriptions to Allergan *Access*® to nearly all physicians who agreed to prescribe its products, it was more sparing in its provision of individualized consulting services through ECBA. Allergan limits its offer of ECBA services to physicians who it believes will prescribe significant quantities of its drugs, particularly Restasis®, as a result of receipt of those services.

215. In certain instances, for exceptionally high-prescribing physicians, Allergan also provides individualized consulting services through BSM Consulting, the same company that assisted in the development of the Allergan *Access*® website. BSM provides similar services to Allergan's internal consulting group, but in some instances, its consultants possess a specific expertise that is of value to a physician.

2. Allergan Required That Physicians Prescribe Its Products in Exchange for Receipt of Its Consulting Services

216. As the preceding descriptions make evident, Allergan's consulting services provided significant value to physicians. In fact, a handout that gives an overview of Allergan's consulting services expressly refers to ECBA's "valuable services." Yet rather than charge physicians for these "valuable services," for years Allergan provided them free of charge.

217. Only recently, around June 2009, did Allergan begin charging for these services, after realizing that free provision of valuable consulting services could expose the Company to liability analogous to that in a recently settled case in which Allergan paid $600 million to settle allegations, among others, that it used value-added reimbursement services to drive off-label sales of Botox®. As ECBA Business Advisor Mike Driscoll explained Allergan's decision to begin charging for its consulting services to sales representatives in Relator's district, "We don't want a target on our backs."

218. Even when Allergan began charging for its consulting services, however, it charged only a nominal fee that was considerably below the market rate. A Level I membership costs approximately $500 and allows the practice use of Allergan *Access*® and its numerous online tutorials. A Level II membership costs approximately $1,000 and allows the practice use of Allergan *Access*®, plus entitles it to two in-person visits per year from an ECBA consultant.

Even when charging, therefore, Allergan continues to gift consulting services of significant value to physicians.

219. Allergan trains its sales representatives to emphasize that the Company provides these services at below-market rates, and that even though physicians are paying Allergan a nominal fee for the services, the Company is still essentially gifting physicians a significant portion of the value of the consulting services. Both Jon Weidner and Mike Driscoll instructed Relator and other sales representatives in his district to convey to physicians that an equivalent external consultant, if paid at market rate, would cost physicians five to ten times more than the ECBA consultant provided by Allergan.

220. Allergan provided these valuable services for free, and continues to provide them at below-market rates, in order to induce physicians to prescribe Allergan drug products — particularly Restasis®, but also Acular LS®, Acuvail®, Zymar®, and Zymaxid®. To implement this strategy, Allergan managers specifically instructed sales representatives to leverage ECBA consulting services to drive sales of Allergan drugs. ECBA services were targeted at specific accounts that managers and sales representatives believed would prescribe greater quantities of Allergan drugs as a result of their receipt of these services.

221. A spreadsheet sent to Relator Wood by Field Sales Trainer William Scruggs on November 26, 2008, shortly after Relator first arrived at Allergan, described ECBA services in multiple instances as part of an "Action Plan" to increase sales:

- Macomb Eye Care Specialists, Clinton Township, Michigan: The Action Plan stated, "We have kit business, but they write 50% Vigamox, in office! GOAL: 100%...clinical and value added. ECBA, Programs…." (all ellipses in

original). Importantly, value-added services such as ECBA are included alongside clinical messaging as a tactic to increase sales;

- Michigan Vision Institute, Flint, Michigan: The Action Plan stated, "Opened practice Oct, 05. Picking up. Did OD program, in of[f]ice 3 days week. Will be a large player Goal: ECBA and sell clinical advantages along [with] est[ablishing a] lasting business relationship." Again, ECBA is included alongside clinical messaging as a tactic to increase sales; and
- DOC Optical Centers, Michigan: The Action Plan stated, "Opened office April, 05 - Dec, 05 total of 465 lasik patients. 2006 claims to see 30 pats week, 120 month. We see no data. Writes both Zymar and Restasis. Started ref program w/in all DOCs 30 locations. A Quota of 2 ref per month. Goal: Get them set with ECBA once data shows, and keep happy, could be top account." The narrative emphasizes that Allergan's provision of ECBA services was contingent on the practice prescribing its products ("once data shows").

222. On multiple occasions, during sales meetings, ECBA Business Advisor Mike Driscoll met with sales districts for approximately an hour each in order to explain how to leverage ECBA services as part of their sales details. Driscoll told sales representatives in Relator's district that ECBA services were reserved for Allergan's "top accounts" and "best customers." The purpose of Allergan's consulting services, Driscoll explained, is to have a "unique offering in the marketplace," something that no other eye care company offers, that will differentiate Allergan from its competition and build loyalty and goodwill among these top practices. Helping clinics in this way, he told them, will drive sales. Taken together, Driscoll's

instructions made clear to sales representatives that only physicians who used primarily Allergan ophthalmic products would receive support from ECBA; customers who used Alcon or ISTA products would not, unless they agreed to change to Allergan products.

223. In an email dated January 22, 2009, Area Manager Scott Youmans instructed sales representatives in his district not to offer the services of ECBA consultant Bob Teale to an account without first consulting Youmans to decide if that account would be an efficient use of Teale's services. Youmans stated that "we want to focus Bob's services on specific accounts. When we discuss the opportunity you've uncovered, we'll decide how we should proceed . . . ." Suggesting that ECBA services were essentially Allergan's offer in exchange for inducing ophthalmologists to prescribe Allergan drugs, he further instructed representatives to look through the list of potential ECBA presentations to determine "what your ECBA can bring to the table." The list of attached presentations covered a wide variety of potential topics, similar to those listed above as available on Allergan *Access*®, including "Financial Benchmarking the Ophthalmology Practice," "Strategic Planning," "Marketing Your Practice," and "Growing Your Dry Eye Practice." Signaling that this use of ECBA services was not unique to Youmans' district, but rather was the standard practice throughout the company, Youmans copied both Allergan's Director of Sales, Stephanie Hayes, and Senior ECBA Manager Richard Morgan on this email.

224. Similarly, on November 12, 2008, ECBA consultant Mike Driscoll sent an email in which he thanked representatives for identifying customers who wished to focus on the "'business of eye care.'" Driscoll had recently completed "ECBA Account meetings" with these physicians and told representatives that "I am sure you will find that your customers will thank you for delivering value to them." Driscoll then recommended that sales representatives follow

up with their physicians by reminding them of the value of Allergan's consulting services by saying, "Dr. Smith, I understand you attended AAO and met with Mike Driscoll, Eye Care Business Advisor…did you find your meeting to be valuable?"

225. In Relator's territory, practices that used Allergan *Access*® and ECBA consulting services included Eye Centers of Ohio, North Canton, Ohio; Summit Ophthalmology, Akron, Ohio; Canton Ophthalmology, Canton, Ohio; and Cleveland Eye Clinic, Cleveland, Ohio. All were top Allergan customers.

226. Allergan's strategy to leverage ECBA consulting services to increase prescriptions of its drug products was effective, and as a result of its free or below-market-rate provision of these services, Allergan successfully induced physicians to prescribe greater quantities of its drug products, many of which were paid for by Government Programs. In November 2008, the Cleveland Eye Clinic ceased prescribing entirely Allergan products (Acular LS® and Zymar®) for its cataract patients and began splitting its prescriptions between Alcon and Allergan products. The clinic indicated that it planned to soon switch to entirely Alcon products. In order to prevent this switch, following a speaking event at the clinic's new surgery center, the head of the ECBA division Richard Morgan met with Thomas Chester, the clinic's optometrist. Morgan signed the clinic up for ECBA services, which on information and belief, was instrumental in the clinic's agreement to continue prescribing a mix of Allergan and Alcon products, rather than switch entirely to Alcon products. Indeed, Chester later expressed great appreciation to Relator for Allergan's provision of the ECBA's consulting services.

227. As a further indication of ECBA's success at driving sales of Allergan products, sales representatives expressed considerable displeasure when the Company announced that it would begin charging for the service, even though it only did so at well-below-market rates.

Representatives regarded, and still regard, Allergan *Access*®, ECBA, and BSM Consulting services among their most important tools to compete with Alcon. Because Alcon leverages its medical device business to gain a competitive advantage for its pharmaceutical products, providing consulting services as an inducement to physicians allows Allergan to, in effect, level the playing field.

3. Allergan Used ECBA Services to Direct Physicians in the Development of "Dry Eye Practices" with Prescribing of Restasis® at Their Core

228. In addition to using consulting services as an outright inducement to physicians to prescribe its products, Allergan also leverages these services to assist ophthalmologists and optometrists in the creation of "dry eye practices" — i.e., practices that specialize in the treatment of dry eye. These practices are naturally conducive to physicians' prescribing of Allergan's Restasis®, and Allergan expects that physicians do so in exchange for its consulting advice.

229. Prior to launch of Restasis®, ophthalmologists or optometrists did not generally treat dry eye — at least not as a large part of their practices — because doing so offered limited opportunity for profit. Ophthalmologists preferred instead to focus their practices around diseases that, when treated with surgical or other complex procedures, generated larger revenues. For patients who did exhibit symptoms of dry eye, ophthalmologists and optometrists generally recommended over-the-counter artificial tears.

230. This status quo — providers' reluctance to specialize in treatment of dry eye coupled with their proclivity to recommend over-the-counter artificial tears when they did — constituted a significant impediment to sales growth for Restasis®, which was the first prescription drug approved for the treatment of dry eye. To overcome that impediment, Allergan

used its free and below-market-rate provision of ECBA consulting services to convince providers that they *could* profitably prescribe Restasis® as part of a dry eye practice.

231. One ECBA presentation, described in an attachment to an email sent by Area Manager J. Scott Youmans, was titled "Growing Your Dry Eye Practice." Its listed objectives included "The Dry Eye Potential," "The Prevalence of Dry Eye Disease," "Financial Opportunity for a Practice," and "Implementing a Dry Eye Standard of Care Plan: 4 Stages." The "Standard of Care Plan" appears to be, in part, an allusion to the prominent role that Allergan® expected Restasis® to hold in the dry eye practice.

232. On April 24, 2009, Relator's District Manager Jon Weidner sent sales representatives in his district a "Continuing Education" piece, titled "Dry Eye Disease in the Optometric Practice," which described the "[o]pportunity" in the market for treatment of dry eye. "[R]eimbursement for a dry eye evaluation can range from $40.00 to upwards of $125.00, with additional payments for each subsequent visit." The article notes that one to three follow up visits may be required, "so optometrists' net revenue for multiple dry eye visits can easily be in the $200 to $700 range."

233. Allergan trained sales representatives to explicitly emphasize to physicians the profit they could make from prescribing Restasis® as part of a dry eye practice. Maria Zanardo, a Field Sales Trainer who trained Relator Wood as part of his ongoing field training in 2010, used a PowerPoint presentation and spreadsheet to show physicians precisely how much revenue they could make for each patient visit and testing procedure, as well as for an overall course of treatment. Zanardo's single-slide PowerPoint presentation showed physicians that they could receive $301 revenue per dry-eye patient, plus another potential $196 for installation of punctual plugs, which are inserted into the tear ducts to block drainage. An accompanying spreadsheet

titled "The Economical Dry Eye" demonstrated the yearly revenue that a physician could make by developing a dry eye practice. The pre-filled values show that a physician treating 400 patients for dry eye will make $48,400 for the initial exam and tests, in addition to $71,600 for follow-up visits, for a total of $120,000 annually.

234. While sales representatives were responsible for broaching the idea of a dry eye practice, and in many instances demonstrating that it could be profitable, ECBA advisors were integral to helping ophthalmologists and optometrists construct a successful one. Sales representatives assured providers that Allergan ECBA advisors were "personal consultants" who would ensure that their dry eye practice was efficiently organized to maximize revenues. In this way, in Relator's territory, ECBA advisors assisted the Novus Clinic in Tallmadge, Ohio, and Summit Ophthalmology in Akron, Ohio, to construct dry eye practices.

235. Allergan also instructed physicians how to code for dry eye treatment in order to maximize their revenue. A document titled "Senior Training Best Practices," which Area Manager Jon Weidner forwarded to sales representatives in his district, describes how to facilitate construction of a dry eye practice by "encourag[ing] the doctor to lissamine green stain EVERY p[atient] for one month." The document continues that by coding 922.85 for "[e]xterior photo with lissamine staining," physicians will receive "37 dollars reimbursement [through insurance] and [M]edicare, plus 2 more visits."

236. To even further grow the revenue that ophthalmologists, and hence Allergan, received through their dry eye practices, Allergan assisted ophthalmologists and optometrists in finding patients for their new dry eye practices by sponsoring community-based patient recruiting events. These events offered patients background information on dry eye disease and encouraged those with symptoms to seek treatment. Allergan provided food, drinks, marketing,

handouts, and general setup assistance. The events were usually non-branded, meaning Allergan did not promote Restasis® and did not disclose that it was a sponsor. Relator did not himself assist with patient recruiting events but knows of other sales representative in his district, including Maria Zanardo, who did, and indicated that they were helpful in building physicians' dry eye practices.

237. That Allergan determined it was profitable to sponsor non-branded patient recruiting events is a testament to its expectation that prescribing of Restasis® would be a central component of the dry eye practices it helped set up. Without exception, in Relator's experience, it was. Ophthalmologists and optometrists' routine prescribing of Restasis® was in part the result of its status as the only prescription dry eye treatment. But it was also the result of sales representatives' continual emphasis to providers of the value that Allergan gave to them by helping them construct their dry eye practices. In this way, the evidence of the profitability of dry eye practices that Allergan presented to providers served dual purposes: as described above, this evidence proved necessary to convince them to set up a dry eye practice in the first place, but it also emphasized, critically, the value of the consulting services being provided by Allergan. While sales representatives were trained not to explicitly demand prescriptions of Restasis® in exchange for ECBA's services, this was nonetheless the implicit agreement. Sales representatives mixed promotion of Restasis® with promotion of ECBA services, and it was understood that ophthalmologists and optometrists who did not prescribe Restasis® would not continue to receive the support of these ECBA services.

4. Allergan's Free and Below-Market-Rate Provision of Consulting Services Resulted in Payments by Government Programs

238. Allergan was aware or reasonably should have been aware that a substantial number of patients seeking treatment for both dry eye and cataract surgery are Medicare Part D and Medicaid beneficiaries, and that as a result of the remuneration it paid to ophthalmologists and optometrists in the form of free or below-market-rate consulting services, these ophthalmologists and optometrists would and did prescribe Restasis®, Acular LS®, Zymar®, and other Allergan products, which would be and were in turn reimbursed by Government Programs.

G. Allergan Used PARx Reimbursement Services to Induce Physicians to Prescribe Restasis® and Other Drug Products

239. Beginning in mid-2009, in conjunction with its provision of ECBA consulting services, Allergan also provided many physicians with free reimbursement support services, contracted through a third party called PARx Solutions, Inc. Allergan supplied PARx services in order to relieve physicians of the potentially substantial cost of processing prior authorizations for its drugs, and thereby induce physicians to prescribe greater quantities of those drugs. PARx offered reimbursement assistance for all Allergan drug products; however, sales representatives primarily promoted it, and subsequently it was primarily used, as a reimbursement aid for Restasis®. As a result, insurance payors, including many Government Programs, paid for prescriptions of Restasis® and other Allergan drugs that they otherwise would not have.

1. Overview of PARx

240. When Allergan first began marketing Restasis®, the drug was not included on most managed care and PBM formularies. As such, payors would not automatically cover the cost of a prescription for Restasis® but instead required a prior authorization. By mid-2009,

when PARx was launched, many payors had eased their formulary restrictions, but in some geographies outside of Relator's territory, payors maintained prior authorization requirements limiting the use of Restasis®.

241. A prior authorization is a request for an insurance company to pay for a drug for a particular patient, even though the company's standard policy may preclude payment for that drug. An insurance company uses a prior authorization as a means to direct patients to more appropriate and/or cost-effective therapies. Prior authorizations allow exceptions to that rule for those patients for whom alternative therapies have been proven to be ineffective or pose too great a risk of adverse events due to concomitantly taken medications or other extenuating circumstances.

242. Generally the physician's staff handles the submission of prior authorizations, which are usually submitted to the patient's insurance company by facsimile, by telephone, or, increasingly, electronically. Staff members dedicate a considerable amount of time to filling out and submitting the forms, as well as to responding to any follow-up issues raised by the payor. Practices have increasingly added a staff member dedicated to processing prior authorizations, which one study found result in a direct cost of $14.24 each to the health care provider. *See* James L. Raper et al., *Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications in an HIV Clinic*, 51 Clinical Infectious Diseases 718 (2010). Factoring in the opportunity cost of work that staff could have instead performed in the absence of the need to complete prior authorizations, the study concluded that the total cost per prior authorization was actually $40.60. *Id.* As payors increasingly curtail payments to providers and squeeze their margins, these costs are significant.

243. The prospect of routine prior authorizations was a particular impediment to physicians' willingness to prescribe Restasis® in those areas that maintained strict formulary restrictions. Given that Allergan's strategy to convince physicians to prescribe greater quantities of Restasis® centered on convincing those physicians of the profitability of implementing a dry eye practice, the prospect of routine prior authorizations significantly undermined that strategy and represented a significant objection to prescribing Restasis®.

244. To mitigate this anticipated objection, Allergan implemented "PARx," a prior authorization assistance program through which Allergan assumed the costs of processing prior authorizations for Restasis® and its other drugs. PARx, as the program was commonly referred to at Allergan, is officially called Prior Authorization Support System, and is run by PARx Solutions, Inc., based in Los Altos, California. PARx Solutions is in turn run by Bio-Ops, Inc., which is also based in Los Altos. A handout given to sales representatives describes PARx as "help[ing] the provider verify patient insurance eligibility and streamlin[ing] the prior authorization process for prescribed products and services not on formulary." Similarly, a "Training Overview" described the "Provider Benefits" of PARx, including "[u]niversal insurance verification and prior authorization processed allowing for greater efficiencies for both the physician and medical office staff."

245. A "cheat sheet" sent to representatives by Ohio Area Manager Jon Weidner on September 8, 2009, outlines how to set up and use a PARx account. In order to receive prior authorization services from PARx, a physician must first sign a "Business Associate Agreement," which allows PARx to access protected patient information. Sign up also requires submission of a "Provider Registration Form," which the "cheat sheet" instructs that the sales

representative should fill out on behalf of the physician. This form contains physician information such as contact details, state license number, DEA number, and tax ID number.

246. Once these forms are submitted and the account is set up, staff can log onto the system under the "provider" tab at www.parxsolutions.com. After clicking "Create New PA Request" and selecting the appropriate product, the user is then promoted to enter the information for the patient requesting the prior authorization. (This information is outlined in detail in a slide deck attached to the email sent by Jon Weidner, referenced *supra*.) The information is then transmitted electronically to PARx.

247. Once PARx receives the patient's information, it handles the entire prior authorization process. Its system automatically selects the appropriate prior authorization form based on the patient's insurance carrier and populates that form with patient and provider information, including information for the requested drug. Most significantly, PARx's staff handles the less formulaic and most time-consuming aspects of the process, including "[d]rug criteria research," "[r]eview of drug denials," and "[f]ollow-up, [s]tatus [c]hecks & appeals." Patients are able to take prescriptions to any pharmacy, and most claims are approved in less than twenty-four hours.

248. The entire service is funded by Allergan and provided free of charge to physicians.

2. Allergan Specifically Targeted PARx To Physicians Who It Believed Would Prescribe the Most Restasis®

249. Allergan sought to leverage PARx's valuable reimbursement services to most effectively generate prescriptions of Restasis® and other drugs. Presumably due to the cost of providing the service, however, there were only a limited number of PARx slots available in

each territory; in Weidner's territory, there were twenty available slots. These, then, were allocated to the physicians who Allergan determined would prescribe the most drugs in exchange for their receipt of free PARx services.

250. In an email dated April 1, 2009, Relator's district manager, Jon Weidner, directed sales representatives to allocate PARx slots to achieve the maximum return on investment for Allergan, stating: "1. Target busy practices with physicians that utilize Restasis 2. Ask the staff member who handles prior authorizations how many they typically do for Restasis, and on what insurance plans 3. Do not commit to them yet, I would like to discuss each account with you first!" Weidner described PARx as one of the "tools to help you get" to "our main goal" of "FINDING NEW GROWTH!" He concluded that "[f]lawless execution of these tools" — PARx among them — "is crucial to our goal of growing NMU's [i.e., new prescriptions]."

251. In another email dated April 24, 2009, Weidner thanked sales representatives "for finding the appropriate office that will benefit from this service that we can provide." Continuing, he described PARx as "a great resource and we need to really sell it and use it to better our relationships with our key offices." By offering PARx to the offices that would receive the most value from it, Weidner sought to obtain the greatest number of Restasis® prescriptions in return. "I would like to get the ball rolling so we [i.e., Allergan] can start to see the benefit sooner rather than later" (emphasis added).

252. Weidner and other managers continually emphasized these same points to sales representatives during sales meetings and teleconferences. PARx, just as the free consulting services provided through ECBA and BSM, was to be utilized as a sales "tool," and as such, strategically used in the way that would most effectively induce physicians to prescribe Allergan's products.

253. Because payors in Relator's territory generally granted Restasis® favorable formulary status and did not require prior authorizations, Relator did not regularly promote PARx as part of his sales detail. However, Phillip Edmondson, a sales representative based in Cincinnati, Ohio (and one of the top sales representatives in the Company), told Relator that he had integrated PARx as a key component of his promotional message. For his exceptional sales performance during 2010, Allergan gave Edmondson an award and a trip to Hawaii.

3. The Office of the Inspector General Has Issued Advisory Opinions that Identify Problems with Free Reimbursement Support Services

254. The Office of Inspector General for the Department of Health and Human Services ("OIG") has provided insight into the legitimacy of reimbursement support services, suggesting that they are highly susceptible to fraud and abuse in Federal Programs.

255. In one 2006 Advisory Opinion, the OIG responded to an inquiry regarding the propriety of a seller of durable medical equipment ("DME") offering free reimbursement consulting services to some of its customers. *See* U.S. Department of Health and Human Services, Office of Inspector General Advisory Opinion No. 06-16 (issued Oct. 3, 2006). The "reimbursement consulting services" at issue included: (i) general claims submission information, such as advice on how to code products; (ii) reviewing claims; (iii) helping to appeal denied claims; and (iv) providing assistance related to medical justification for receiving particular products. *Id.* at 2. The OIG concluded that these reimbursement services constituted, at a base level, remuneration, and that because the DME suppliers were "in a position to generate Federal health care program business" for their customers, the offering of such services "clearly" implicated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). *Id.* at 4.

256. The OIG further noted that the reimbursement services at issue "would be neither limited in nature, nor free-standing," concluding that the free services "would potentially confer substantial independent value upon the DME supplier." *Id.* at 5. The OIG stated that any assistance "securing Federal reimbursement for individual beneficiaries to receive particular products could cause beneficiaries to receive greater quantities of, or more expensive" products than they actually require. *Id.* In addition, such reimbursement services would tend to provide a financial incentive to steer customers to purchase the supplier's products, "even if products from other manufacturers were less expensive or more appropriate." *Id.*

257. The PARx reimbursement services provided by Allergan operate in a way that is directly analogous to the DME scenario described in the OIG's Advisory Opinion. As described *supra*, PARx services "confer substantial independent value" upon physicians, as well as provide financial incentives for physicians to prescribe Restasis® rather than suggest less expensive, and in many cases more appropriate, over-the-counter remedies. In practice, Allergan's provision of PARx services free of cost to physicians has caused physicians to prescribe (and patients, including Government beneficiaries, to use) Restasis® rather than suggest less expensive, and in many cases more appropriate, over-the-counter remedies. Thus, as was the case in the DME scenario evaluated by the OIG, PARx served as a "vehicle to pay unlawful kickbacks" to physicians who were expressly selected by Allergan in order to increase sales.

258. In a second Advisory Opinion, the OIG determined that *any* services, including pre-authorization services, that save a physician's office staff time, or that result in a realization of savings, or that were designed to refer or induce the purchase of a manufacturer's products, could constitute unlawful remuneration and implicate the Federal Anti-Kickback Statute. *See* U.S. Department of Health and Human Services, Office of Inspector General Advisory Opinion

No. 10-04 (issued Apr. 30, 2010). Services provided by Allergan through PARx meet all three of the preceding criteria.

4. Allergan Intended for Its Provision of Free Reimbursement Services to Induce Physicians to Prescribe Restasis® and Other Drugs, and Therefore Violated the Anti-Kickback Statute

259. Allergan's provision of free reimbursement services through PARx precisely mirrors the reimbursement services that the OIG's advisory opinions found could implicate the AKS. Further, while OIG's advisory opinions were precluded by a lack of knowledge of the sponsoring companies' intent from finding that the programs in question did in fact violate the AKS, in this case it is clear that Allergan *did* intend for its free provision of reimbursement services to induce physicians to prescribe Restasis® and other drugs, and in turn to cause Government Programs to reimburse for those prescriptions. Allergan's repeated instructions to sales representatives to allocate PARx services to high-prescribing and potentially high-prescribing physicians who Allergan believed would write additional prescriptions as a result of their receipt of these services, confirm that Allergan intended as much.

260. On information and belief, Amgen was successful in its intention to use PARx to induce physicians to prescribe Restasis® and other drugs, which it knew or reasonably should have known would cause Government Programs to reimburse for those prescriptions, and therefore violated the federal AKS, 42 U.S.C. § 1320a-7b(b).

261. By engaging in the above-described Fraudulent Kickback Scheme, through a pattern of corrupt and illegal conduct, with the intent to induce physicians to prescribe its drug products that Allergan knew or should have known would be reimbursed by Government Programs, Allergan violated the Federal AKS, 42 U.S.C. § 1320a-7b(b).

262. The Fraudulent Kickback Scheme described above constitutes violations of the AKS, made with the intent to induce physicians to prescribe Allergan drug products that were reimbursed by Government Programs, through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729. Moreover, Allergan's kickbacks caused pharmacies submitting claims to the Government to falsely certify compliance with applicable laws and regulations, including that the claims were not tainted by illegal kickbacks.

VIII. THE FRAUDULENT MARKETING SCHEME WITH REGARD TO ACUVAIL®, ZYMAR®, AND ZYMAXID®

A. Allergan Untruthfully Promoted Acuvail® as Superior to Other Ketorolac Formulations for Treatment of Pain and Inflammation Following Cataract Surgery

263. In late 2009, both Acular® and Acular LS® faced imminent competition from generic equivalents. In order to stem a rapid loss of sales, Allergan sought to convert patients from Acular® and Acular LS® to its recently approved follow-on formulation of ketorolac, Acuvail®. The goal, as conveyed in an email forwarded by multiple district managers, was to convert "ALL of our accounts from Acular LS to Acuvail." In order to do so, Allergan claimed that Acuvail® demonstrated superior safety and efficacy to other ketorolac formulations — particularly Acular LS®, which had far greater sales than Acular® — despite the fact that there is no substantive evidence demonstrating that Acuvail® is superior to either Acular® or Acular LS®.

1. Allergan Trained Sales Representatives to Promote Acuvail® as Superior to Acular® and Acular LS®

264. From August 24th through 27th, 2009, Allergan ophthalmology sales representatives from across the country gathered for the "Acuvail™ Launch Meeting" at the Hyatt Regency, in Dallas-Fort Worth, Texas, where Allergan trained sales representatives how to

promote Acuvail®. Sales representatives were taught a promotional message that centrally focused on superiority claims versus Acular LS®. As Relator Wood's handwritten notes reflect, representatives were told that Acuvail® was an "upgrade" from previous ketorolac formulations, and that it demonstrates a "[d]ramatic difference" and "[b]ehaves different clinically" from these other formulations. At another point during the meeting, again reflected in Relator Wood's handwritten notes, sales representatives were instructed to promote Acuvail® to ophthalmologists as a "unique formulation [that] behaves differently and is engineered for superior outcomes for your patients."

265. Even prior to the launch meeting, this superiority message had been prefaced at meetings and in emails, as managers repeatedly emphasized to sales representatives that they should sell Acuvail® as an "upgrade" to Acular® and Acular LS®. During his introductory presentation at the Dry Eye-External Disease National Sales Meeting, on June 22, 2010, Vice President of Sales Joseph Schultz told sales representatives gathered from across the country that "what we need to do with this portfolio is clearly continue to upgrade the Acular® users to Acuvail®.".

266. On July 31, 2009, Senior Marketing Programs Associate Lori Bledsoe sent an email to all ophthalmology sales representatives regarding preparations for the Acuvail® product sample program. Bledsoe instructed representatives to "[b]egin *upgrading* your customers to ACCUVAIL [sic] now" and "[s]ubmit renewal contracts as your customers agree to *upgrade* to ACUVAIL" (emphases added).

267. In an email sent on August 3, 2009, three weeks before the launch meeting, ACUVAIL™ Senior Product Manager Mary Ellen Esgro provided ophthalmology sales representatives across the country with an "ACUVAIL™ Launch Checklist," which instructed

them to "[f]ocus on *upgrading* the Diamond Targets to ACUVAIL NOW" (emphasis added). "Diamond Targets" were high-prescribing physicians selected by management as early targets for conversion to Acuvail®. The checklist also noted that "Diamond Targets can start *upgrading* post-op sheets" to include Acuvail® rather than Acular LS® (emphasis added). Only three days later, on August 6, 2009, Esgro sent another email in which she described a promotional visit as an "ACUVAIL™ upgrade service call."

268. At the launch meeting, sales representatives were trained to support managers' assertions that Acuvail® was an "upgrade" to Acular® and Acular LS® by claiming that Acuvail® was more tolerable than Acular LS®, and resulted in less burning and stinging. This claim, however, was based largely on theory and lacked supporting clinical evidence. Managers told sales representatives, and trained them to in turn tell physicians, that the lack of the preservative BAK in Acuvail®, as well as the addition of carbomethylcellulose ("CMC") (an ingredient also found in over-the-counter artificial tears), resulted in superior tolerability of Acuvail® versus Acular LS®. However, the only clinical evidence that supported Allergan's superiority claim was a phase I titration study, which was not adequate to provide a meaningful clinical comparison of adverse events. Nonetheless, managers trained sales representatives to claim that the study "showed Acuvail [was] more tolerable [than] Acular LS."

269. Sales representatives were also trained to promote Acuvail® as more effective than previous formulations of ketorolac, again based on theoretical benefits of the addition of CMC. CMC, sales representatives were told, "increase[s] contact time [with] lower pH," results in "more drug to target tissues," "prolongs drug retention," and "promotes wound healing." The overall result, they were told, was that Acuvail® more effectively inhibits inflammation than does Acular® or Acular LS®.

270. Superiority claims also pervaded Allergan's printed promotional materials, which were based on the theme "A Cut Above Our Best." The Acuvail® "Launch Packet" received by sales representatives was titled "A Cut Above Our Best, The ketorolac molecule enhanced, the NSAID advanced." The front page displays four diamonds, increasing in size and clarity from left to right. Under the last, largest, and brightest diamond is printed "Introducing Acuvail." The letter that follows, from senior Allergan managers, again describes Acuvail® as "**a cut above our best**" (emphasis in original), and refers to the "exclusive benefits offered by ACUVAIL™."

271. During the meeting, sales representatives engaged in role play exercises during which they practiced using the Acuvail® sales aid to promote Acuvail® to physicians. The sales aid, which was also based on the "Cut Above Our Best" theme, facilitated sales representatives' delivery of the superiority messages on which they had been trained. Under the header "Introducing your next NSAID," the sales aid read "A Cut Above Our Best" and displayed three diamonds, again ascending in size and clarity from left to right. Making the superiority message even more explicit, a later page was titled "The Ketorolac Molecule Enhanced," and described Acuvail® as "Designed With Outcomes in Mind."

272. An annotated version of the same sales piece stated that "ACUVAIL™ ophthalmic solution was a cut above our best in: "Outcomes," "Innovation," "Convenience," and "Comfort." As support for each of these claims, the annotated sales piece cited the Acuvail® Prescribing Information, despite the fact that the Prescribing Information contains no comparison of Acuvail® to alternate formulations of ketorolac. As sales representatives were trained, the targets of Allergan's superiority claims were alternate formulations of ketorolac, not the vehicle, sans active ingredient, against which Acuvail® was compared in its clinical registration trial. The sales piece further instructed sales representatives, "[w]hen physicians ask what enhancements to

the ACUVAIL™ formation allow the product to achieve this complete clearance, offer the optimized pH as an explanation." This "explanation" was indicative of the theoretical justifications that Allergan used in lieu of actual clinical evidence to support its superiority claims.

273. An annotated version of the Acuvail® Prescribing Information provided to sales representatives included similar claims. The introduction instructed sales representatives that "you are selling a diamond in the class of ophthalmic NSAIDs." Accompanying comments described Acuvail®'s pH as "[p]recisely engineered to help facilitate performance" and the addition of CMC as "a crucial part of the ACUVAIL formulation" that provides "[i]mproved patient comfort." Again, Allergan trained its sales representatives that these comparisons of Acuvail® were directed against alternate ketorolac formulations, not against the vehicle to which Acuvail® was actually compared in clinical trials.

274. As described *infra* in part 3 of this section, both Allergan's safety and efficacy superiority claims were false, misleading, and unsupported by any substantive clinical evidence. Nonetheless, multiple Allergan managers, including Vice President of Sales Dave LeCause, as well as regional and district managers from across the country, witnessed and did not object as these superiority claims were continually reiterated to sales representatives and became the core of their promotional message to physicians.

2. Earnings Calls Confirm That Allergan's Senior Management Was Responsible for the Implementation of the Acuvail® Superiority Campaign

275. As indicated by the presence of senior managers as well as regional and district managers from across the country at the Acuvail® Launch Meeting, Allergan's management was not only aware of, but supported, the unsubstantiated superiority claims made by the Company's

sales representatives. Earnings call transcripts confirm that Allergan's senior management regarded these superiority claims as an integral component of its strategy to convert all Acular® and Acular LS® prescriptions to Acuvail® prior to generic availability of the former.

276. The "Presentation Summary" of a July 31, 2009, earnings call, which was held shortly before the launch of Acuvail®, stated that "ACUVAIL has the advantage of … very low level of burning and stinging upon application vs. Acular…." Transcript, Event Brief of Q2 2009 Allergan Earnings Conference Call – Final (July 31, 2009), *available at* LEXIS FD (Fair Disclosure) Wire.

277. On a later call following the launch of Acuvail, Allergan Chairman and CEO David Pyott told investors, "ACUVAIL is perceived as a real product improvement relative to Acular, … with additional comfort due to its formulation…." Transcript, Q3 2009 Allergan Earnings Conference Call – Final (Oct. 29, 2009) , *available at* LEXIS FD (Fair Disclosure) Wire. To the extent that physicians "perceived" Acuvail®'s formulation as an "improvement relative to Acular," they did so only because Allergan had systematically and illegally promoted to them that it was.

278. In another call, Pyott stated that "full emphasis is being placed on the product advantages of our latest generation product, ACUVAIL." Transcript, Q4 2009 Allergan Earnings Conference Call – Final (Feb. 4, 2010), *available at* LEXIS FD (Fair Disclosure) Wire.

3. Allergan's Claims that Acuvail® Was Superior to Acular® and Acular LS® Were False and Misleading

279. Despite the centrality of superiority claims to its promotion of Acuvail®, Allergan lacked substantial evidence or substantial clinical experience to support them. While the annotated sales aid received by sales representatives cited Acuvail®'s Prescribing Information as

evidence that Acuvail® demonstrated superior outcomes to other formulations of ketorolac, in fact, Acuvail® was only studied in comparison to, and shown to be superior to, its delivery vehicle, not an alternate formation of ketorolac. No well-controlled, head-to-head studies were conducted comparing Acuvail® to alternate formations of ketorolac.

280. Instead, as described above, Allergan based its superiority claims on the theory that the lack of BAK and addition of CMC resulted in increased tolerability and efficacy. Such theoretical justifications, however, fail to perceive the myriad complexities in the body's reaction to any drug, and in addition, may be subject to manipulation by those with a vested interest in the outcome. It is for these reasons that the FDA requires clinical evidence of a drug's observed rather than predicted effect.

281. The only clinical evidence that supports Allergan's claim that Acuvail® results in less burning and stinging than Acular LS® is a phase I titration study. Early-stage titration studies are designed to determine an appropriate dose for a drug; however, they do not contain sufficient patients and are not otherwise suitable to make a meaningful comparison of adverse event profiles between drugs.

282. On August 25, 2010, the FDA sent Allergan a Warning Letter, citing the Company for its misleading promotion of Acuvail® as superior to alternate formulations of ketorolac. The letter was sent specifically in regard to a print advertisement, similar to the one described *supra*, that portrayed Acuvail® as "The Ketorolac Molecule Enhanced." The FDA wrote that the advisement "*misleadingly* suggests that Acuvail confers more therapeutic benefits and has been 'enhanced' in comparison to other ketorolac products or other ocular non-steroidal anti-inflammatory drugs (NSAIDS)" (emphasis added). The letter continued,

> FDA is not aware of any substantial evidence or substantial clinical experience to support claims implying that Acuvail has been 'enhanced' in any way or is superior to other ocular ketorolac products or other ocular NSAIDs in treating pain and inflammation following cataract surgery, or in any other outcomes, including enhanced patient comfort.

The FDA also criticized Allergan for its misleading citation of the Acuvail® Prescribing Information as evidence that Acuvail® resulted in "'enhanced patient comfort,'" stating that the Prescribing Information "does not include any supportive evidence." On the contrary, "the adverse reactions section of the [Prescribing Information] specifically states that patients using Acuvail experienced adverse events, such as ocular pain, headache, and blurred vision (1-6% of patients), which could undermine patient comfort."

283. Contrary to Allergan's repeated claims and the tenuous findings of its titration study, other evidence suggests that Acuvail® actually results in *more* burning and stinging than Acular LS®. As conveyed in the drugs' respective Prescribing Information, in clinical trials, patients taking Acuvail® reported a 1.5% incidence of burning and stinging, while patients taking Acular LS® reported *no* burning and stinging. While this comparison is indirect, given the lack of other reliable evidence, it does cast doubt on the accuracy of Allergan's superiority claim.

284. Anecdotal evidence also supports that Acular LS® is better tolerated than Acuvail®. On multiple occasions, Relator made sales calls to physicians who dosed themselves with Acuvail® and Acular LS® in order to judge their relative tolerability. Those who did so consistently described Acular LS® as the more comfortable of the two ketorolac formulations. Relator has also dosed himself with both products and concurs with the opinions of these physicians: while he found Acular LS® to feel roughly equivalent to an artificial tear, Acuvail® resulted in noticeable discomfort.

4. Allergan Used Bonus Payments to Incentivize Sales Representatives to Promote Acuvail® as Superior to Acular LS®

285. Allergan leveraged bonus payments as an incentive to sales representatives to deliver to physicians the unsubstantiated superiority claims that it had trained them to deliver. Beginning in 2010, immediately following the launch of Acuvail, Allergan changed the incentive compensation for the Blue and Gold teams so that 25% of their potential incentive compensation was based on total units of Acuvail® prescribed. Likewise, 20% of area managers' incentive compensation was based on total units of Acuvail® prescribed. Neither sales representatives nor area managers received any additional compensation for additional prescriptions of Acular® or Acular LS®, leaving them, as Allergan intended, with a strong incentive to promote Acuvail® as superior to Acular® and Acular LS®.

5. Allergan's False and Misleading Promotion Caused Physicians to Prescribe Acuvail® Instead of Cheaper Generic Alternatives

286. In the absence of Allergan's misleading and untruthful claims that Acuvail® was superior to Acular® and Acular LS®, there would have been little if any reason for physicians to prescribe Acuvail® instead of the cheaper, generic equivalent of Acular LS® with which they were familiar. It was, however, physicians' lack of any such impetus to change their prescribing habits that necessitated Allergan to fabricate an impetus in order preserve market share in the face of generic competition. As a result of its fabrication, physicians prescribed and Government Programs reimbursed prescriptions of Acuvail® that they had no reason to, and otherwise would not have prescribed and reimbursed.

B. Allergan Promoted Zymar® and Zymaxid® Off-Label for Prevention of Endophthalmitis in Conjunction with Cataract Surgery

287. Allergan extensively promoted Zymar® and Zymaxid® for routine use pre- and post-cataract surgery to prevent endophthalmitis. It did so despite the FDA's limited approval of both drugs for only the treatment of bacterial conjunctivitis, and despite the lack of substantial clinical evidence showing that Zymar® and Zymaxid® were effective for prevention of endophthalmitis. On the contrary, the available clinical evidence demonstrates that Zymar® does not reach sufficiently high concentrations in the relevant portions of the eye to effectively prevent endophthalmitis, and no evidence demonstrates that the increased active ingredient in Zymaxid® remedies Zymar®'s failure. Nonetheless, Allergan leveraged its sales representatives, paid speakers, advertorials, and selective dissemination of clinical literature to mislead ophthalmologists into believing that both drugs were effective for this off-label use, and thereby established prophylactic use of topical antibiotics in conjunction with cataract surgery as the standard of care.

1. Clinical Evidence Demonstrates that Zymar® and Zymaxid® Are Ineffective for Prevention of Endophthalmitis

288. Ophthalmologists' prescribe topical anti-infective agents in conjunction with cataract surgery primarily in order to prevent exogenous endophthalmitis, which is an inflammation of the ocular cavities caused by the direct introduction of bacteria or other infectious agent. Most cases of endophthalmitis related to cataract surgery result from contamination by patients' own conjunctival flora — i.e., bacteria on the surface of the eye, which enter the interior of the eye during surgery. *Staphylococcus epidermidis* and *Staphylococcus aureus* are responsible for most cases of endophthalmitis in conjunction with cataract surgery. Though rare — estimates of incidence vary but are generally around 0.2% —

endophthalmitis is an extremely serious complication that is difficult to treat even when detected early, and may result in blindness.

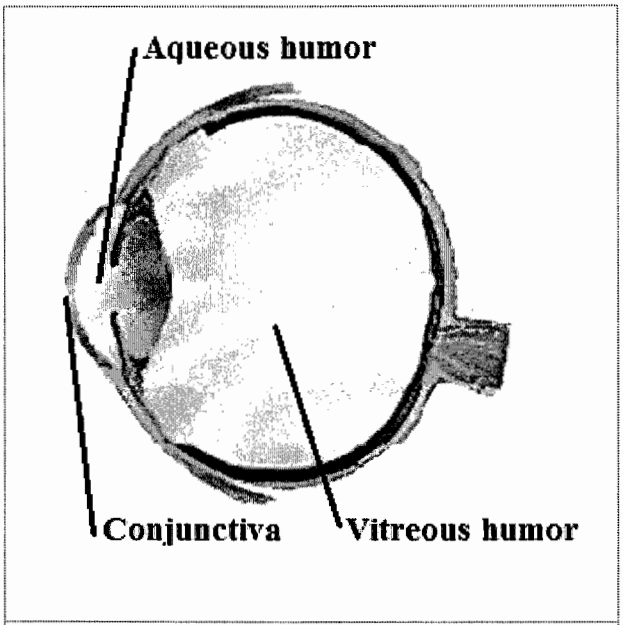
289. In the United States, the use of topical antibiotics for the prevention of endophthalmitis is common despite the lack of credible evidence supporting this practice. Because of the rarity of the disease, multi-center controlled clinical trials would be difficult to conduct; however, even smaller trials have failed to provide clinical support of topical antibiotics' effectiveness for prevention of endophthalmitis. The only large trial of the effectiveness of a topical antibiotic for the prevention of endophthalmitis that included a clinical outcome measure, found that the topical antibiotic was at best minimally effective.

290. Lacking substantial evidence, in order to promote Zymar® and Zymaxid® for prevention of surgically related endophthalmitis, Allergan has relied on retrospective analyses and selective use of "proof-of-principle" studies (i.e., studies suggesting that prophylaxis *should* work, even in the absence of direct evidence that it does). The retrospective analyses, however, were too marred by confounding variables to reach meaningful conclusions, and a more holistic survey of available proof-of-principle studies provides strong evidence that Zymar® and Zymaxid® are not effective for this use.

(a) **Zymar® does not reach sufficient concentrations in the aqueous humor to effectively prevent endophthalmitis**

291. Bacterial conjunctivitis — which the FDA has approved Zymar®, Zymaxid®, and other topical anti-infectives to treat based on substantial clinical evidence — is a disease of the surface of the eye. As such, in cases of bacterial conjunctivitis, topically administered antibiotics easily reach the site of infection at relatively high concentrations. In contrast, endophthalmitis is caused by infection in the aqueous and/or vitreous humors, which requires

that a topically administered anti-infective substantially penetrate the eye in order to be effective. Moreover, it must be able to reach the interior in great enough quantity to resist dilution caused by the rapid turnover of intraocular fluids, particularly in the vitreous humor.



Anatomy of the eye.

292. The available clinical evidence shows that Zymar® does not reach a sufficient concentration in the aqueous humor, let alone in the vitreous humor, to prevent endophthalmitis. A recent prospective, randomized study of three topical antibiotics found that none (including gatifloxacin 0.3%, the active ingredient in Zymar®) reached the concentration in the aqueous humor necessary to prevent endophthalmitis. Eric D. Donnenfeld et al., *Human aqueous humor concentrations of besifloxacin, moxifloxacin, and gatifloxacin after topical ocular application*, 37 J. Cataract & Refractive Surgery 1082 (2011). Patients were administered one drop of medication 60 minutes prior to surgery, based on the assumption that antibiotic "concentrations at 60 minutes would reasonably approximate the maximum drug levels achieved in aqueous

humor after dosing." *Id.* at 1086. Aqueous humor samples were obtained immediately prior to surgery, and the concentrations of antibiotics in these samples were compared to the MIC_{90} of *Staphylococcus epidermidis* and *Staphylococcus aureus*, the most common causes of surgically related endophthalmitis. MIC_{90} stands for "minimal inhibitory concentration" and is the concentration necessary to kill or prevent the reproduction of 90% of the given bacteria.

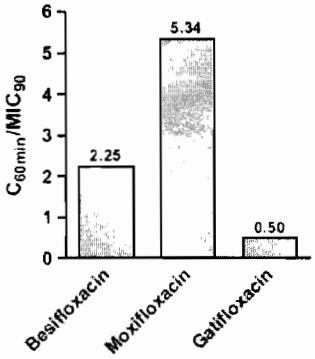


Figure 1. Ratio of fluoroquinolone C_{60min} in the aqueous humor to MIC_{90} for methicillin-susceptible *S epidermidis* and *S aureus* isolates from recent ocular infections (ratios were identical in both species). MIC_{90} values were 0.06 µg/mL, 0.125 µg/mL, and 0.25 µg/mL for besifloxacin, moxifloxacin, and gatifloxacin, respectively, for both *S epidermidis* and *S aureus*.[31]

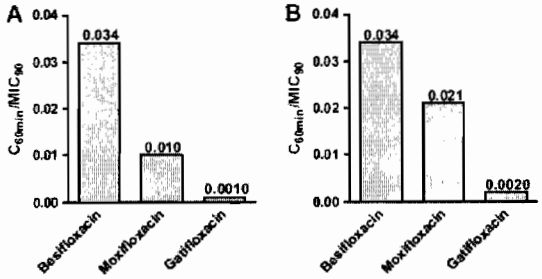


Figure 2. Ratio of fluoroquinolone C_{60min} in the aqueous humor to MIC_{90} for methicillin-resistant and fluoroquinolone-resistant *S epidermidis* (A) and *S aureus* (B) isolates from recent ocular infections. MIC_{90} values for besifloxacin, moxifloxacin, and gatifloxacin, respectively, were 4 µg/mL, 64 µg/mL, and 128 µg/mL against *S epidermidis* and 4 µg/mL, 32 µg/mL, and 64 µg/mL against *S aureus*.[31]

Donnenfeld et al., at 1086.

293. As seen in the graph above, gatifloxacin reached only 50% of the MIC_{90} for antibiotic-susceptible strains of *Staphylococcus epidermidis* and *Staphylococcus aureus*. *Id.* Gatifloxacin fell even further short of the "mutant prevention concentration" ("MPC"), which is the concentration necessary to prevent the development of antibiotic resistance among surviving bacteria, and is generally eight to ten times the MIC_{90}. More troubling, with regard to increasingly prevalent strains of antibiotic-resistant bacteria, gatifloxacin reached only 0.1% and 0.2% of the MIC_{90} for *Staphylococcus epidermidis* and *Staphylococcus aureus*, respectively. *Id.*

294. These concentrations, the authors concluded,

> were insufficient to expect therapeutic efficacy against the recent drug-resistant pathogens often identified in postoperative endophthalmitis. This is a critical finding because resistance to fluoroquinolones (older and newer fluoroquinolones) among gram-positive isolates from endophthalmitis cases has increased in the past decade from approximately 30% to as much as 50%.

Id. at 1087. Neither more frequent dosing or the addition of BAK (a preservative that may also increase antibiotic potency) would be sufficient to remedy these substantial shortfalls. *Id.* Recommending against postoperative use of topical antibiotics for prevention of endophthalmitis, the authors stated that "intention should be directed toward eradication of the causative pathogens on the ocular surface before they gain entry to the eye." *Id.* at 1088.

295. A number of other studies support the conclusions of the Donnenfeld study that Zymar® does not reach sufficient concentrations in the aqueous humor to prevent endophthalmitis. In one such study, even Zymar® dosed four times in the hour prior to cataract surgery reached an average concentration of only 0.77 µg/ml, far less than the MIC of fluoroquinolone-resistant *Staphylococcus aureus* of 3.5 µg/ml. Sirel Gür Güngor et al., *Aqueous humor penetration of moxifloxacin and gatifloxacin eye drops in different dosing regiments before phacoemulsification surgery*, 95 Brit. J. Ophthalmology 1272, 1273-74 (2011). Zymar® did exceed the MICs of various non-resistant bacteria, *id.* at 1274, although it only managed to do so at a dosing frequency that far exceeds what is practical and safe for long-term pre- and post-surgical use, as Allergan recommended that ophthalmologists prescribe. The study demonstrated that reduced dosing frequency substantially lessened the intraocular concentration that Zymar® achieved. *Id.* at 1273.

296. A study by Teshigawara et al. similarly found that gatifloxacin administered four times in a two-hour pre-surgical period failed to reach the MIC_{90} of major pathogens of

endophthalmitis including *Enterococcus faecalis* (MIC_{90}: 0.50), *Propionibacterium acnes* (MIC_{90}: 0.50), *Pseudomonas aeruginosa* (MIC_{90}: 1.0), *Staphylococcus epidermidis* (MIC_{90}: 1.0), and methicillin-resistant *Staphylococcus aureus* (MIC_{90}: 64). Takeshi Teshigawara et al., *Penetration of Gatifloxacin Eye Drops into the Aqueous Humor in Humans*, 15 *Ocular Immunology and Inflammation* 309, 312 (2007). "The mean concentration of [gatifloxacin] in [the] aqueous humor was 0.485 ± 0.328 μg/mL." *Id.* Although the study does not explicitly state so, gatifloxacin failed by an even greater margin to reach the MPC for all the preceding bacteria, as well as non-methicillin-resistant *Staphylococcus aureus* (MIC_{90}: 0.12).

297. Similar findings were presented by Dianne H. Kim et al., *Aqueous Penetration and Biological Activity of Moxifloxacin 0.5% Ophthalmic Solution and Gatifloxacin 0.3% Solution in Cataract Surgery Patients*, 112 Am. Academy Ophthalmology 1992 (2005).

298. In the Harper study, the authors recovered 59 specimens of coagulase-negative staphylococcal bacteria, which had been retrieved from endophthalmitis patients and preserved in a specimen bank. Tom Harper et al., *In Vitro Efficacy and Pharmacodynamic Indices for Antibiotics against Coagulase-Negative Staphylococcus Endophthalmitis Isolates*, 114 Am. Academy Ophthalmology 871 (2007). These preserved bacterial specimens were then tested to determine their susceptibility to antibiotics, including gatifloxacin, and that susceptibility was then compared to the mean aqueous concentration of the antibiotics observed in other clinical literature.

299. The study found that topically administered gatifloxacin failed to achieve the concentration necessary to inhibit the tested bacteria, reaching only 34% of the MIC_{50}, and a mere 2% of the MIC_{90}. *Id.* at 873. "[T]he most favorable clinical outcomes occur when the pharmacokinetic index (C_{max}/MIC_{90}) is approximately 8 to 10," *id.*, meaning that gatifloxacin

would need to reach a concentration 400 to 500 times higher than it actually did in order to achieve this ideal clinical outcome. The authors conclude that "the current study suggests that the fluoroquinolones may not offer ideal prophylaxis against [coagulase-negative staphylococcal bacteria], the most common organism isolated in postoperative endophthalmitis. The use of perioperative antibiotics is widespread despite the lack of evidence and controversy surrounding their use." *Id.* at 874.

(b) **Zymar® does not reach sufficient concentrations in the vitreous humor to effectively prevent endophthalmitis**

300. The preceding studies examined the ability of gatifloxacin to reach adequate concentration in the aqueous humor; however, endophthalmitis is an infection of the whole eye, and in order to best prevent infection, a topical antibiotic needs to also reach adequate concentration in the vitreous humor. Allergan's own training manual, titled "Ocular Infections," noted that "the most common site of endophthalmitis is in the vitreous cavity of the eye…." As such, "[t]he best prophylaxis for postoperative endophthalmitis would be an antibiotic that reaches therapeutic levels in the vitreous humor." Patrick Costello et al., *Vitreous Penetration of Topical Moxifloxacin and Gatifloxacin in Humans*, 25 Retina 1, 4 (2005). Given gatifloxacin's failure to reach sufficient concentration in the aqueous, it is unsurprising that gatifloxacin also failed to reach sufficient concentration in the vitreous, which is located posterior to the aqueous.

301. In the Costello study, two groups of patients were administered gatifloxacin at different dosing frequencies; the first group was administered three doses in the hour preceding cataract surgery, and the second self-administered gatifloxacin four times daily for three days preceding surgery. *Id.* at 2. In both groups, the vitreous concentration of gatifloxacin at the time of surgery was "lower than the MIC_{90} for the commonest bacterial pathogens." *Id.* at 3. In the

group administered gatifloxacin immediately prior to surgery, the vitreous concentration averaged 0.001 µg/ml, and in the extended three-day-dosing group, the vitreous concentration averaged 0.008 µg/ml. In comparison to the MIC_{90} of *Staphylococcus aureus* (MIC_{90}: 0.11 µg/ml) and *Staphylococcus epidermidis* (MIC_{90}: 0.09 µg/ml), the concentrations reached by gatifloxacin "were 11 to 220 times below their respective MIC_{90} levels." *Id.* at 4. Although the study does not explicitly note as much, it may be extrapolated that these concentrations were approximately 110 to 2200 times below the mutant prevention concentration, which is approximately eight to ten times the MIC_{90}.

302. These results only further the author's introductory comment that "[t]here is currently no strong evidence to suggest that the administration of preoperative topical antibiotics reduces the incidence of postoperative endophthalmitis." *Id.* at 3. Rather, the evidence firmly supports that pre- and post-surgical administration of gatifloxacin does not prevent post-surgical endophthalmitis.

(c) There is no evidence to show that Zymaxid® reaches sufficient concentrations in the aqueous and vitreous humors to prevent endophthalmitis

303. All the studies examining the concentration reached by gatifloxacin in the aqueous and vitreous humors concern the 0.3% concentration of the drug (i.e., the concentration in Zymar®). No published studies examine the concentration reached by Zymaxid® (gatifloxacin 0.5%) in the aqueous and vitreous humors. However, while the higher concentration of active ingredient in Zymaxid® undoubtedly allows Zymaxid® to achieve intraocular concentrations greater than those achieved by Zymar®, given the degree by which Zymar® failed to achieve the concentrations needed to serve as an effective prophylaxis, it is almost certain that Zymaxid®'s increased concentration is insufficient to remedy Zymar®'s

failure. Even if Zymaxid® reached increased concentrations in the aqueous and vitreous that were perfectly proportionate to its increase in active ingredient relative to Zymar® — i.e., a 66% increase — the intraocular concentrations reached by Zymaxid® would still fall far short of the MIC_{90} and MPC of methicillin-resistant staphylococci in the aqueous humor, as well as MIC_{90} and MPC of both resistant and non-resistant bacteria in the vitreous humor. As such, available evidence supports that Zymaxid® is similarly ineffective for prophylaxis of postsurgical endophthalmitis.

(d) **Retrospective analyses do not provide substantial evidence that use of topical antibiotics in conjunction with cataract surgery prevents endophthalmitis**

304. As described in greater detail *infra*, Allergan trained its sales representatives to promote and distribute the Jensen study, Michael K. Jensen, *Third-and fourth- generation fluoroquinolones: Retrospective comparison of endophthalmitis after cataract surgery performed over 10 years*, 34 J. Cataract & Refractive Surgery 1460 (2008), to ophthalmologists as evidence of Zymar®'s effectiveness for prevention of postsurgical endophthalmitis, as well as its superiority to Vigamox® for this use.

305. As a retrospective analysis, however, rather than a prospectively designed trial, the Jensen study was ill-equipped to provide meaningful evidence of the conclusions that Allergan used it to promote. Retrospective analyses lack randomization among treatment groups, and it is therefore difficult to determine if observed differences among groups were caused by the variable of interest (in this case, the topical antibiotic chosen), or if those differences were instead caused by one of innumerable other variables that influence outcomes. Correlation between the variable of interest and other unmeasured variables may, and frequently does, result

in systematic bias, creating the impression that the studied variable drove the observed outcome, when in actuality that outcome was driven by other unobserved variables.

306. The endophthalmitis rate among cataract surgery patients is affected by numerous variables, including local bacteria species, the preoperative sterilization regimen, and the skill of the performing surgeon, among others. The values of many of these variables change with time. The significant variance in the endophthalmitis rates observed in the Jensen study, even between adjacent time periods, reasonably implies that a host of factors contributes to patients' surgical outcomes. For instance, from March 1, 2001, through May 30, 2002, all studied patients received the third-generation fluoroquinolone ofloxacin and experienced an endophthalmitis rate of 0.30 cases per 1,000 patients. From July 1, 2002, through August 30, 2003, patients continued receiving ofloxacin but the observed endophthalmitis rate quadrupled to 1.29 cases per 1,000 patients.

307. This massive variance in endophthalmitis rates made the Jensen study's conclusion highly sensitive to the study's design and (since it was a retrospective study lacking in predefined outcome measures) to the author's decisions. In a published comment, James P. McCulley expressed suspicion that Jensen, "a well-known paid speaker for Allergan," had manipulated the study's design in order to produce a favorable result for Zymar®. James P. McCulley, Comment, *Fluoroquinolones and postoperative endophthalmitis*, 35 J. Cataract & Refractive Surgery 206 (2009). McCulley's suspicion appeared to be heightened by the study's "several serious flaws," including its "meager statistical analysis," the opacity of much of its analysis, and its failure to consider numerous potentially "confounding factors." *Id.*

(e) **The only large prospective trial that examined effectiveness of a topical antibiotic for prophylaxis of endophthalmitis using a clinical-outcome endpoint found that a topical antibiotic was at best minimally effective for the prevention of endophthalmitis**

308. Due to the rarity of postsurgical endophthalmitis, prospective clinical trials examining the prophylactic effectiveness of topical antibiotics require large patient populations, and would therefore be extremely expensive to conduct. The only prospective clinical trial that has been conducted was a European study, which compared the effectiveness of topical administration of an antibiotic, versus intraocular injection of an antibiotic, versus no treatment. Peter Barry et al., *ESCRS study of prophylaxis of postoperative endophthalmitis after cataract surgery*, 32 J. Cataract & Refractive Surgery 407 (2006). 13,698 patients were randomized among four treatment groups to receive either (1) an intraocular injection of the cephalosporin antibiotic cefuroxime combined with perioperative topical application of the third-generation fluoroquinolone levofloxacin; (2) only topical application of levofloxacin; (3) only intraocular injection of cefuroxime; or (4) no prophylactic treatment. *Id.* at 408.

309. The study concluded that there was no statistically significant difference in endophthalmitis rates between patients who received topical antibiotics and those who received no prophylactic treatment. *Id.* at 409.

310. In contrast, patients who received an intraocular injection of cefuroxime experienced such superior results that the trial was halted early. *Id.* The clear superiority of the intraocular route of administration, which results in a higher intraocular concentration of antibiotic, demonstrates the importance of a high concentration to effective prophylaxis. This in turn bolsters the proof-of-principle analysis *supra*, that Zymar® and Zymaxid®'s failure to

achieve sufficient concentrations in the aqueous and vitreous humors makes them ineffective for prophylaxis of endophthalmitis.

(f) **Numerous experts have concluded that no substantial evidence supports use of topical antibiotics in conjunction with cataract surgery for the prevention of endophthalmitis**

311. Despite the ostensible ubiquity of studies examining the effectiveness of gatifloxacin for prevention of postsurgical endophthalmitis, these studies are of such poor quality that even in aggregate, they fail to provide evidence of the effectiveness of Zymar® or Zymaxid® for this use. On the contrary, the available evidence supports the conclusion that Zymar® and Zymaxid® are ineffective for this use. A number of experts, having examined the whole of the evidence, agree.

312. A widely-cited study from 2002 examined all of the clinical evidence available to support common methods of prophylaxis of endophthalmitis. Thomas A. Ciulla et al., *Bacterial Endophthalmitis Prophylaxis for Cataract Surgery*, 109 Ophthalmology 13 (2002). It determined that the only prophylactic measure to receive an intermediate clinical recommendation of "B," meaning the recommendation was found to be "moderately important to clinical outcome," was administration of pre-operative povidone-iodine, a very cheap antiseptic available since the mid-1950s. *Id.* at 17. All topical antibiotics received the lowest recommendation of "C," meaning "cannot be definitely related to clinical outcome." *Id.* at 18.

313. Another review concluded similarly that there was lacking evidence of topical antibiotics' effectiveness as prophylaxis for endophthalmitis. Thomas J. Liesegang, *Perioperative Antibiotic Prophylaxis in Cataract Surgery*, 18 Cornea 383, 390 (1999). The study noted that, given the limited ability of topical antibiotics to maintain sufficiently high concentrations in the anterior of the eye, administration of topical antibiotics "serves mainly to

alter conjunctival flora." *Id.* "Conjunctival flora" refers to bacteria located on the membrane of the eye, which would generally be responsive to the alternative prophylaxis of povidone-iodine. Even so, Liesegang concluded any potential usefulness of topical antibiotics for this purpose is limited to administration immediately preceding the operation: "there is no rationale in the general or ophthalmic literature supporting the use of postoperative antibiotics, especially after 24 h[ours]." *Id.* at 393.

314. An editorial written by Oliver Schein in 2007, four years after the introduction and widespread adoption of Zymar®, determined that there was still "no sound evidence base" for the regular use of topical antibiotics pre- and post-cataract surgery. Oliver D. Schein, *Prevention of Endophthalmitis after Cataract Surgery: Making the Most of the Evidence*, 114 Ophthalmology 831, 831 (2007). As the basis for his conclusion, Schein referred not only to the dearth of any credible affirmative evidence of topical antibiotics efficacy for this use, but also to the results of two large European studies (one of which is discussed *supra*), which "both suggest that perioperative topical antibiotics confer minimal or no benefit." *Id.*

315. These unbiased experts therefore reached the same conclusion that was presented in the preceding argument, that there is inadequate evidence to support routine use of Zymar® and Zymaxid® for prevention of endophthalmitis. However, as described below, Allergan misleadingly skewed the available clinical evidence to promote that Zymar® and Zymaxid® had been shown to be effective for this use.

2. Allergan Used Paid "Advertorials" to Promote Zymar® to Ophthalmologists for the Prevention of Endophthalmitis

316. Allergan used "advertorials" to promote Zymar® off-label as effective for the prevention of endophthalmitis in conjunction with cataract surgery, and to recommend that

ophthalmologists therefore prescribe Zymar® as an integral part of patients' pre- and post-surgical regimens. Advertorials are Allergan-sponsored supplements to industry trade magazines that include articles written by paid Allergan consultants or by ghostwriters under the name of paid Allergan consultants. These articles were, in effect, promotional pieces for Zymar® and other Allergan products, and routinely presented selective or otherwise misleading depictions of the available clinical evidence. However, because these promotional articles were presented in a format that mirrored that of the overall trade magazine, and because the authors' financial relationships with Allergan were disclosed either not at all or only in fine print, the advertorials presented a façade of scientific merit, which made them all the more effective as promotional pieces for off-label use of Allergan's products.

317. In April 2006, Allergan sponsored a supplement to EyeWorld, which describes itself as the "News Magazine of the American Society of Cataract & Refractive Surgery," an influential and academic association of ophthalmic surgeons. The paid supplement included the article *Gatifloxacin Effectively Prevents Endophthalmitis* by Luis E. Fernandez de Castro, in which de Castro summarized a study that he conducted regarding the effectiveness of Zymar® to prevent endophthalmitis in New Zealand white rabbits. In the study, which was unpublished at the time, rabbits were administered saline solution in one eye and gatifloxacin in the other, and then injected with a non-antibiotic-resistant form of *Staphylococcus aureus*. Eyes treated with gatifloxacin "demonstrated significantly less inflammation, infection, and culture positive endophthalmitis compared to those of the control animals." The authors extrapolated that "[t]his indicates that topical prophylaxis with gatifloxacin can reach levels in the anterior chamber that can reduce bacterial numbers," although they did not state what the actual intraocular concentration were or how those concentrations compared to the MIC_{90} for the bacteria

responsible for most cases of endophthalmitis. The authors also did not note that a number of dissimilarities between rabbit and human eyes, including rabbits' larger conjunctival sac, thinner cornea, reduced tear production, and lower blink rate, all result in higher drug penetration and concentration than in the human eye. As such, the article's omission to reference the already published Kim study, *see* ¶ 297 — which was conducted in human subjects and found that the aqueous concentration of gatifloxacin was significantly lower than the MIC_{90} for fluoroquinolone-resistant bacteria, as well as significantly lower than the mutant prevention concentration for fluoroquinolone-sensitive bacteria — is particularly glaring. The supplement did not disclose whether Dr. de Castro or any of the other authors received consulting or speaking fees or other financial compensation from Allergan.

318. In August 2006, Allergan sponsored another supplement to EyeWorld titled *Optimizing Cataract Outcomes*. The supplement included an article by John Wittpenn, M.D., titled *Preventing Endophthalmitis*, which began, "The single best management of endophthalmitis is prevention," and stated that "numerous studies have demonstrated that both gatifloxacin (Zymar, Allergan) and moxifloxacin (Vigamox) achieve aqueous concentrations higher than the MIC_{90} levels for organisms commonly implicated in ocular infections." In support of this statement, the article cited four trials, although only one of these (McCulley) actually measured the aqueous concentration of gatifloxacin. Contrary evidence is not referenced. The article concluded that "we have better drugs today to prevent endophthalmitis than we had 10 years ago." The supplement also included continuing medical education credit, which included the question, "Which of the following is true regarding post-surgical endophthalmitis?" Based on the information in Dr. Wittpenn's article, the answer is (b): "Fourth-generation fluoroquinolones such as gatifloxacin and moxifloxacin attain intraocular

levels high enough to kill typical pathogens." Dr. Wittpenn received "a retainer, ad hoc fees, or other consulting income from Allergan, Inc." Even though ACCME and FDA guidelines prohibited the supplement from being promotional in nature because CME credit was offered, the supplement was nonetheless blatantly promotional, as well as off-label.

319. In February 2008, Allergan sponsored an insert to Cataract & Refractive Surgery Today titled *Best of Source: Superior Outcomes through Refractive and Cataract Education*. The leading article by Eric D. Donnenfeld, M.D., was titled *Methicillin-Resistant* Staphylococci *in Cataract and Refractive Surgery*. As Donnenfeld noted in the article, methicillin-resistant *Staphylococcus aureus* and *Staphylococcus epidermidis* account for the majority of endophthalmitis outbreaks in conjunction with cataract surgery. In response to this threat, Donnenfeld recommended that cataract surgeons prescribe gatifloxacin. He cited the Moshirfar study, Majid Moshirfar et al. *Endophthalmitis after Uncomplicated Cataract Surgery with the Use of Fourth-Generation Fluoroquinolones*, 114 Ophthalmology 686 (2007), as "the first clinical evidence that cataract patients' incidence of endophthalmitis was approximately 50% lower for those who received gatifloxacin 0.3% compared with moxifloxacin ophthalmic solution 0.5%...." Donnenfeld did not note that the Moshirfar study was a retrospective analysis, meaning its methodology was therefore significantly flawed; that it did not include a placebo comparator; and, most misleadingly (given Donnenfeld's claim that gatifloxacin resulted in 50% fewer cases of endophthalmitis compared to moxifloxacin) that there was no statistically significant difference between treatment groups. Donnenfeld nonetheless concluded that "[u]ntil I see a human endophthalmitis study with different results, I will consider this one the best guide for choosing an antibiotic," thereby foregoing any discussion of whether antibiotics were effective in the first place. In fact, Donnenfeld presents the ESCRS study, which is the best

evidence that topical antibiotics are *ineffective* for treatment of endophthalmitis, *see* ¶¶ 308-10, as evidence of the *general* effectiveness of antibiotics for prevention of endophthalmitis, noting that the study showed a "78% reduction of endophthalmitis with intracameral cefuroxime." However, he misleadingly omits that the study demonstrated no comparative benefit for *topical* antibiotics, which were the topic of Donnenfeld's article. This same Donnenfeld article was again included in a March 2008 supplement to Cataract & Refractive Surgery Today titled *Premium Cataract Surgery (Not just for premium IOLs.)*.

3. Allergan Trained Its Sales Representatives To Falsely and Misleadingly Promote That Zymar® and Zymaxid® Are Effective for Prevention of Endophthalmitis

320. Recognizing that Zymar® and Zymaxid®'s on-label markets for bacterial conjunctivitis were relatively small, Allergan trained its sales representatives to promote both drugs for prevention of endophthalmitis, despite evidence that they were ineffective for this use.

321. For example, in 2006, Allergan paid Kathy Osvath from The Wellington Group, Inc., a medical education and communications company located at 390 Claymont Drive, Earlysville, Virginia, to develop training materials, which were then provided to the entire Zymar® sales force. Allergan used these materials to provide sales representatives with background on endophthalmitis, in preparation for their promotion of Zymar® for that use to cataract surgeons. The materials explained that endophthalmitis is

> an ocular infection that occurs when bacteria or toxins make their way to the inside of the eye during the surgical procedure. Although endophthalmitis is rare (estimated to range between 5 and 10 cases per 10,000) the rates appear to be increasing, possibly due to the increase in clear corneal incisions. Half of all affected patients end up with marked loss of visual acuity.

Acknowledging the lack of clinical evidence supporting use of Zymar® for prevention of endophthalmitis, the materials nonetheless stated that its use was "generally believed" to be appropriate for this use:

> Because endophthalmitis is generally caused by organisms that are normally found within the patient's own flora (two strains of Staphylococcus: *aureus* and *epidermidis*, commonly found in the eyelids, are responsible for 80% to 90% of all endophthalmitis cases), and because it is so difficult to perform well-controlled studies to investigate the cause of endophthalmitis, health care providers have little evidence-based data on how best to prevent the development of the condition. However, it is generally believed that a combination of topical antibiotic and anti-inflammatory agents should be administered to the patient before, during, and after ocular surgery, accompanied by the implementation of a number of perioperative and environmental precautions

(emphasis added). Again, despite the lack of supporting evidence, Allergan reinforced that "the current practice is to use appropriate-spectrum topical antibacterial agents such as fluoroquinolones [like Zymar®] both before and after surgery to help prevent postoperative infections such as endophthalmitis and keratitis."

322. As part of his new-hire training for Zymar®, Relator Wood was trained on multiple types of eye infections, including endophthalmitis. A PowerPoint presentation from this training noted that endophthalmitis "[o]ften occurs as a complication of cataract surgery." Relator Wood's "Basic Training" materials posed the question, "Why Have Ophthalmologists Moved to Fourth-Generation Fluoroquinolones?" like Zymar® and Zymar®. In response, sales representatives were trained that Zymar® had "distinct advantages" in the prevention of endophthalmitis.

323. During Relator Wood's new-hire training, managers trained sales representatives that the two bacteria responsible for most cases of postoperative endophthalmitis are

Staphylococcus epidermidis and *Staphylococcus aureus*, and that Zymar® effectively eradicates both pathogens. Following the instruction of their trainers, sales representatives then engaged in role play exercises during which they practiced conveying that same information to physicians, then asking the physicians, "Why wouldn't you use Zymar® to prevent endophthalmitis?" This was a key message in sales representatives' detailing of Zymar®, and sales representatives practiced delivering it as part of role play exercises at numerous sales meetings that Relator Wood attended while employed by Allergan.

324. The instructions provided to sales representatives were in violation of Allergan's own Compliance Manual, which states that "[a]ll Allergan promotional programs, activities and associated materials must be consistent with FDA-approved product labeling." Compliance Manual at 11. The Compliance Manual also directs that all free samples must be provided with the intention that they will be used on-label:

> Allergan must provide all samples with the intent that the health care professional will administer the drug for uses consistent with our FDA-approved product labeling. Samples should not be given to any health care professional who is reasonably certain to use the drug in an off-label manner.

Compliance Manual at 98. Contrary to its own directive, Allergan instructed its sales representatives to provide Zymar® and Zymaxid® samples to numerous physicians who Allergan was aware performed exclusively cataract surgery.

4. Allergan Selectively Used the Jensen Study to Misleadingly Promote That Zymar® and Zymaxid® Are Effective for Prevention of Endophthalmitis

325. The Jensen study was a retrospective analysis, conducted by a regular paid speaker for Allergan, that concluded Zymar® was both effective and superior to Vigamox® for prevention of endophthalmitis in conjunction with cataract surgery. As described *supra* in part 1

of this section, ¶¶ 304-07, the study was greatly flawed, and Allergan's selective use of it to promote Zymar® as effective for prevention of endophthalmitis was highly misleading.

326. Nevertheless, Allergan trained its sales representatives to use this and other Washington Legal Foundation ("WLF") reprints as a key part of their sales details to ophthalmologists. Relator Wood's notes from a training session, reflecting what sales representatives were instructed, describe off-label WLF reprints such as the Jensen study as "1/2 [representatives'] main selling points." During role play exercises at multiple sales meetings, representatives practiced, under the direction of their managers, proactively using the Jensen study to promote Zymar® as both effective and superior to Vigamox® for prevention of endophthalmitis in conjunction with cataract surgery.

327. In a presentation to the Allergan sales force dated January 19, 2009, Sales Trainer Michael Sweeney directed sales representatives to use the Jensen study to promote Zymar® as superior to Vigamox® for the prevention of endophthalmitis: "This article can be used both as evidence of clinical superiority for 4th generation fluoroquinolones versus 3rd generation fluoroquinolones, as well as significant evidence that Zymar® (gatifloxacin) is superior to Vigamox® (moxifloxacin) in preventing endophthalmitis."

328. By not providing sales representatives with any information to the contrary, managers implied to representatives that the Jensen study represented definitive evidence of Zymar®'s effectiveness for this off-label use. Sales representatives were not provided with, did not include in their role plays, and did not inform ophthalmologists that additional evidence showed that Zymar® was not effective for prophylaxis of endophthalmitis. As such, Allergan's promotional messages not only violated FDA regulations prohibiting proactive off-label promotion, but also violated FDA regulations requiring fair balance.

329. In addition to training sales representatives to incorporate the off-label message of the Jensen study into the verbal promotion of Zymar®, Allergan shipped thousands of reprints of the Jensen study, which sales representatives were instructed to proactively provide to cataract surgeons, whether or not those surgeons initiated discussion of the use of Zymar® for prevention of endophthalmitis. Based on directions received from sales and marketing management, Allergan's sales representatives have provided thousands of copies of the Jensen Study to health care professionals throughout the country. This is just one example of Allergan's illegal use of reprints in the off-label promotion of Zymar®.

330. Allergan's use of the Jensen study to proactively promote Zymar® for off-label use violated the Company's own compliance policy, which restricts sales representatives' use of journal reprints (including "WLF Reprints") in the promotion of its drug products:

- "Allergan representatives must only disseminate pre-approved reprints. Do not detail any part of the reprint for the health care professional, including the title or the names of the authors.
- "Allergan representatives must provide reprints in their original envelope. Do not open, highlight or add detail to reprints.
- "Sales representatives may not use either on-label or off-label reprints to prompt a physician to ask an off-label question or to start an off-label discussion."

Compliance Manual at 14.

5. Allergan Promoted Zymar® and Zymaxid® to Cataract Surgeons, Who Do Not Treat Bacterial Conjunctivitis

331. In furtherance of its Fraudulent Marketing Scheme, Allergan provided its sales representatives with "call lists" of ophthalmologists to whom representatives were instructed to promote Zymar®. The ophthalmologists on these call lists included cataract and refractive surgeons who Allergan knew did not treat Zymar® and Zymaxid®'s on-label indication of bacterial conjunctivitis, but rather, as Allergan again knew, would prescribe the drugs as a result of Allergan's off-label promotion for the prevention of endophthalmitis. Signaling the centrality of this off-label promotional message to Allergan's overall promotion of Zymar® and Zymaxid®, representatives' call lists did not even include primary care physicians, who treat the majority of cases of the drugs' on-label indication of bacterial conjunctivitis.

332. By directing ophthalmology sales representatives to dedicate their promotional efforts to physicians who prescribed Zymar® and Zymaxid® almost exclusively for off-label use, Allergan reinforced the message that sales representatives learned during training, that they were expected to promote Zymar® and Zymaxid® off-label for the prevention of endophthalmitis in conjunction with cataract surgery.

6. Allergan Incentivized Its Sales Representatives to Promote Zymar® and Zymaxid® Off-Label

333. To further incentivize sales representatives as part of its Fraudulent Marketing Scheme, Allergan implemented quota and bonus programs that rewarded sales representatives for promoting Zymar® and Zymaxid® off-label, to physicians who Allergan knew only prescribed Zymar® and Zymaxid® off-label. The quota and bonus programs were instituted and have been applied to sales representatives, district managers, regional managers, and vice presidents. Sales-based bonuses and pay increases constitute a significant portion of total

compensation for Allergan's sales personnel, and Allergan knows that its quota and bonus programs create a strong incentive for sales representatives to promote Zymar® and Zymaxid® off-label and for sales managers to ensure that sales representatives do so.

334. Allergan's quota system required that ophthalmology sales representatives promoted Zymar® and subsequently Zymaxid®, to all physicians on their call lists regardless of specialty. Bonus payments were rewarded based on sales of Zymar® or Zymaxid®. Because, as Allergan knew, the physicians on representatives' call lists did not and would not prescribe Zymar® or Zymaxid® for on-label use, the only way that sales representatives could achieve the targets set by Allergan, and subsequently receive incentive payments, was to promote Zymar® and later Zymaxid® for off-label use.

335. Allergan set sales representatives' quotas based, in part, not just on the quantity of Zymar® and Zymaxid® already prescribed in their territory but on the total quantity of all anti-infectives, including Vigamox®. Because, as Allergan knew, the vast majority of Vigamox® prescriptions written by ophthalmologists were for off-label use, sales representatives were required to promote Zymar® and Zymaxid® off-label in order to "convert" these Vigamox® prescriptions to Zymar® or Zymaxid®, and thereby reach their sales quota.

336. It is largely the result of Allergan's incentive scheme that sales representatives long promoted Zymar®, and later Zymaxid®, off-label for the prevention of endophthalmitis.

7. Allergan Used Paid Speakers to Conceal and Extend Its Off-Label Promotion of Zymar® and Zymaxid®

337. Allergan knew that under FDA laws and regulations it was not permitted to use promotional speaker programs to initiate discussion of off-label uses of Zymar® or Zymaxid®. According to its own Compliance Manual, such promotional programs "must be consistent with

FDA-approved product labeling and must be accurate, true and balanced." Compliance Manual at 76. Off-label information may only be shared "in response to an unsolicited request for such information from a health care professional." *Id.* at 77.

338. Nevertheless, as part of its Fraudulent Marketing Scheme, Allergan routinely used paid experts to influence ophthalmologists to prescribe Zymar® and Zymaxid® off-label for the prevention of endophthalmitis in conjunction with cataract surgery. These paid speakers were known as "Key Opinion Leaders," meaning they were physicians who influenced the opinions and prescribing practices of their peers.

339. Before Allergan paid a physician to give a promotional presentation for Zymar® or Zymaxid®, that physician was required participate in Allergan-sponsored training. Tellingly, these training programs were coordinated by Allergan's sales and marketing department, not its medical affairs department. The training sessions typically occurred at resort-style locations and included extensive instruction on off-label uses of Zymar® or Zymaxid®, including for the prevention of endophthalmitis in conjunction with cataract surgery. Speakers-to-be were paid to participate in these off-label training sessions.

340. Allergan selected the topics for its speakers' presentations. Although it had its own approved slide deck that it provided for speakers' use, Allergan routinely permitted speakers to incorporate their own slides, which often described off-label uses and data. Paying physicians to give these off-label promotional presentations for Zymar® and Zymaxid® was a common and widely-accepted sales practice at Allergan.

341. For example, Dr. Mitchell Jackson, founder and Medical Director of Jackson Eye in Lake Villa, Illinois, and a Key Opinion Leader and consultant to Allergan, was a regular speaker for Allergan at numerous promotional programs throughout the country. Jackson was an

ophthalmologist specializing in cataract and refractive surgeries who gave on average fifty to one-hundred speaker programs for Allergan each year. He was paid $2000 per program.

342. For example, on December 8, 2009, Jackson gave a program at Johnny's Downtown Restaurant, 1406 West 6th Street, Cleveland, Ohio, to eight ophthalmologists. The primary topic of the program was Acuvail®, but during the presentation, as was his regular practice, Jackson discussed his routine off-label use of Zymar® pre- and post-operatively for prophylaxis of endophthalmitis in cataract and refractive surgeries. Jackson's off-label promotion was proactive, i.e., not in response to a question from the audience.

343. Despite their official responsibility for doing so, during his time at Allergan, Relator Wood never witnessed another sales representative or manager object to a speaker's proactive discussion of off-label content during a paid promotional presentation. Were he to have objected to a speaker's proactive discussion of off-label content, Relator Wood believes that he would have been reprimanded by his manager, and potentially fired.

IX. ALLERGAN'S ILLEGAL MARKETING AND KICKBACK ACTIVITIES CAUSED THE SUBMISSION OF FALSE CLAIMS TO FEDERAL PROGRAMS AND *QUI TAM* STATES

344. Defendant's Fraudulent Kickback Scheme was successful and played a substantial role in securing hundreds of thousands of prescriptions for Allergan's drugs in exchange for Allergan's distribution of free drug products and supplies. As a result, improper and illegal claims were submitted for reimbursement by Government Programs, and those claims were reimbursed.

345. Defendant Allergan's Fraudulent Marketing Scheme served its intended purpose of inducing doctors to write off-label prescriptions for Zymar® and Acular LS® and inducing the submission of claims for reimbursement of those prescriptions by Government Programs. As

Allergan intended, Government Programs subsequently did, in fact, reimburse those claims for off-label uses.

346. At least in part as a result of Allergan's illegal sales and marketing practices, Zymar® and Acular LS® have been heavily used off-label for the treatment of Medicaid, Medicare Part D, Veteran's Administration, and other Federal Program participants.

347. Allergan knew, and expected, that its schemes would result in Government Program reimbursements for its drugs. Allergan closely tracked the various third party payors that reimbursed its drug products. These sources included government payers such as Medicaid and Medicare. For the Allergan drugs that were reimbursed by Government Programs under retail and/or mail-order pharmacy benefit programs, Allergan's unlawful schemes resulted in misbranded or tainted prescriptions that were presented to these pharmacies. These pharmacies then submitted these false or fraudulent prescription claims to the federal or state program responsible for approving and facilitating reimbursement of the false claims.

348. In the case of Medicaid, retail pharmacies were engaged in providing pharmaceutical services to Medicaid recipients throughout the United States. Many of the retail pharmacy services are provided under contractual agreements with the *Qui Tam* States through their Medicaid provider licensure program, whereby the pharmacies agree to provide pharmaceuticals to the *Qui Tam* States' Medicaid patients, and the *Qui Tam* States in turn reimburse the pharmacies for their costs plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicaid patients.

349. Pharmacies periodically (e.g., once per day) submit their Medicaid claims for reimbursement by "batching them" and submitting them electronically to the *Qui Tam* States (or in some cases, claims are initially submitted to Medicaid Managed Care plans). These claims

include the claims for off-label prescriptions for the Allergan drugs as well as claims tainted by Allergan's illegal kickbacks. As such, the pharmacies unwittingly make false certifications and false claims directly to the *Qui Tam* States concerning Medicaid reimbursement on a daily (or periodic) basis.

350. As part of each electronic claim, the pharmacies affix their unique Medicaid provider identification numbers, which serve as electronic stamps indicating that (as Medicaid providers) they are in compliance with all applicable federal and state laws. The pharmacies are then reimbursed on a monthly basis by the *Qui Tam* States for all approved claims.

351. The *Qui Tam* States are not financially responsible for paying one-hundred percent of the pharmacies' claims for reimbursement. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily low-income and disabled persons.

352. The federal involvement in Medicaid includes providing matching funds and ensuring that the states comply with minimum standards in the administration of the program. The federal share of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on each individual state's per capita income compared to the national average. Among the states, the FMAP is at least 50 percent, and in some instances, as high as 77 percent. Through the FMAP process, state Medicaid administrators obtain the Federal Government's share of the pharmacies' reimbursements by submitting a quarterly Form 64 to CMS. For this reason, claims submitted to state Medicaid agencies, including those in the *Qui Tam* States, are presented to the Federal Government within the meaning of the FCA.

353. The federal government pays Medicaid claims through a continuing line of credit certified by the Secretary of the Treasury in favor of the state payee. 42 C.F.R. § 430.30(d)(3), (4). The federal government authorizes the state payee "to draw Federal funds as needed to pay

the Federal share of disbursements." 42 C.F.R. § 430.30(d)(3). The state can draw down on those funds only to pay the Medicaid claims of health care providers. 42 C.F.R. § 430.30(d). The funds made available to the state thus remain federal funds, in a Federal Reserve account, until they are drawn by the state and used to pay the pharmacies' claims.

354. The Federal Government also "approves," within the meaning of the FCA, the claims submitted and paid through the Medicaid program. When a state presents its Form 64 (i.e., the quarterly report of actual expenditures) to CMS, the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were appropriate. If CMS determines that certain claims paid by the state were improper, CMS may recoup the amount of the erroneously expended funds by reducing the amount of money provided to the state during the next quarter. Because the Form 64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state, these reports overstate the amount of federal funds to which the state was entitled by the amount fraudulently paid.

355. These are, therefore, false records or statements knowingly caused to be made or used by Allergan to get false claims paid and approved by the United States in connection with the Medicaid program.

356. In the case of Medicare, retail pharmacies were engaged in providing pharmaceutical services to Medicare Part D recipients throughout the United States. Many of the retail pharmacy services are provided under contractual agreements with Medicare Part D contractors, whereby the pharmacies agree to provide pharmaceuticals to Medicare-eligible patients, and the Part D contractors reimburse the pharmacies for their costs plus a fixed

dispensing fee meant to provide the pharmacies with a profit for providing services to Medicare patients.

357. In 2006, with the advent of Medicare Part D, for beneficiaries dually eligible for both Medicaid and Medicare programs, the pharmacies' false claims for reimbursement were submitted to contractors designated by and under contract with the United States as Medicare Prescription Drug Plans ("PDPs"). Allergan's schemes inflated Medicare Advantage Prescription Drug Plans ("MA-PDPs") and PDP drug costs, thereby causing increased Medicare Part D drug costs.

358. Effective January 1, 2006, Medicare Part D prescription drug coverage for eligible senior enrollees has been provided through MA-PDPs and stand-alone PDPs administered by private companies, usually health insurers or pharmacy benefit managers. These Part D programs are subsidized by the federal government, which covers the cost of drug payments. The false or fraudulent drug claims were then included in drug utilization data submitted by plan sponsors to CMS through Prescription Drug Event ("PDE") records.

359. These false claims embedded within the PDE records were then paid or approved by CMS pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. CMS makes payments to plan sponsors on a monthly basis through estimated subsidy payments and, where needed, at year-end as a result of the payment reconciliation process. The reconciliation process compares estimated subsidy payments made to plan sponsors throughout the year with the cost data submitted by plan sponsors through PDE records to determine any additional residual payments required by CMS to be paid to MA-PDPs and PDPs.

360. CMS payments made through the Part D subsidy process, or as a result of additional residual payments to MA-PDPs and PDPs, included payments for false claims that were knowingly caused to be submitted as a result of Allergan's unlawful schemes.

361. Allergan knew that its unlawful schemes would cause third parties to create materially false records, statements, or claims that would be used to improperly obtain reimbursement or payment from Government Programs, including Medicaid and Medicare.

X. ALLERGAN CAUSED GOVERNMENT PROGRAM PROVIDERS TO FALSELY CERTIFY COMPLIANCE WITH THE LAW

362. As described in this Second Amended Complaint, Allergan not only caused pharmacies to submit false claims, Allergan also caused physicians and pharmacies to falsely certify their compliance with applicable laws which require express and implied certifications of compliance with conditions of payment.

363. Allergan also caused physician-providers to falsely certify their compliance in connection with their receipt of kickbacks, including free drugs, supplies, and related inducements in connection with Allergan's promotion of dry eye practices.

364. As to Medicaid, state Medicaid provider agreements include requirements that participating pharmacies and physician providers comply with all laws, rules, and regulations governing the Medicaid program, including compliance with the AKS. These agreements also include provisions that the pharmacies agree that the submittal of any claim by or on behalf of the pharmacy will constitute a certification that the medical services for which payment is claimed were furnished in accordance with the requirements of Medicaid, and that the information submitted in, with, or in support of the claim is true, accurate, and complete.

365. The Medicaid program expressly prohibits reimbursement for claims that are for off-label indications — i.e., are not medically necessary — and claims submitted as a result of kickbacks. As alleged in this Second Amended Complaint, Allergan's illegal schemes caused the Medicaid-participating pharmacies and physician-providers to falsely certify their compliance with all laws, rules, and regulations governing the Medicaid program, including the anti-kickback laws, which prohibit an entity from knowingly and willingly offering, paying, soliciting, or receiving any remuneration to induce the referral of individuals or the purchase of items or services for which payment may be made under Medicare, Medicaid, or other federal or state health programs. These certifications were express, were a condition of payment or reimbursement by Government Programs, and were material to the government's decision to pay or reimburse for the Allergan drugs.

366. As to Medicare, physician-providers must sign agreements in which they agree to abide by all applicable Medicare laws and regulations, and certify their understanding that reimbursement of claims under Medicare is conditioned on compliance with the AKS. These certifications are also included in the claim forms themselves, *see, e.g.,* Forms CMS-855A and CMS855I. Thus, reimbursement for Medicare requires compliance with the Anti-Kickback Statute.

367. As to Medicare for the pharmacies and Medicare Part D contractors, they are required to abide by and certify compliance with all laws, rules, and regulations governing the Medicare program. *See* e.g. 42 C.F.R. § 423.505(k)(3). When submitting claims data to CMS for payment, Part D plans (and their subcontractors) must certify that the claims data is true and accurate to the best of their knowledge and belief, which includes the absence of any false claims such as those prohibited by the False Claims Act. As alleged in this Second Amended

Complaint, Allergan's illegal schemes caused the Medicare Part D plans to falsely certify their compliance with all laws, rules, and regulations governing the Medicare program, including the False Claims Act and the anti-kickback statute, 42 U.S.C. § 1320a-7b(b). These certifications were express, were a condition of payment or reimbursement by Government Programs, and were material to the government's decision to pay or reimburse for the Allergan drugs.

368. Allergan knowingly caused pharmacies and Part D plans to falsely certify compliance with applicable laws, rules, and regulations, which caused state and federal Government Programs to reimburse or pay for Allergan's drugs not otherwise eligible for reimbursement or payment.

XI. ALLERGAN ACKNOWLEDGED ITS VIOLATION OF THE ANTI-KICKBACK STATUTE AND CHANGED ITS BUSINESS PRACTICES

369. In a series of steps — in late 2008, June 2010, and finally again in January 2011 — Allergan announced it was changing its long-standing business practices of providing free CCKs, and free drug shipments, out of concern that they were illegal.

370. Allergan's first change occurred in late 2008, when it announced to its sales force via conference calls that it would cease providing CCKs to ophthalmologists, since providing the kits could be viewed as an inducement to use Allergan products. According to a PowerPoint presentation, dated November 13, 2008, which Allergan presented to its sales force regarding the decision (a) CCKs would no longer be available; (b) sales representatives would no longer be able to assist physicians to create "patient instruction sheets," although Allergan continued to pay for them, as well as the free prescription pads, through the JG Pads website; and (c) large quantities of free drugs would only be available for the top 1,000 accounts through "Direct Sample Ship" agreements (the 1,000-account limit was quickly dropped due to push-back from

sales personnel). In the presentation, Allergan acknowledged that its long-standing business practice of providing free CCKs to ophthalmologists was unlawful: "[P]hysician's acceptance of free kits can be interpreted as being in violation of Federal Anti-Kickback statutes."

371. In lieu of the free kits, Allergan announced its new policy was to charge its ophthalmologist customers a fee for each kit or part thereof. However, Allergan continued its business practice of proving free drug shipments, customized prescription pads, customized patient instruction sheets, and free consulting and reimbursement assistance.

372. Then, as described above, on or about June 18, 2010, Allergan announced to its sales force that Allergan would no longer continue to provide free drug shipments to physicians because the practice may be interpreted by the government as an illegal inducement. As a result, Allergan reduced the quantity of free drugs it provided physicians to conform with the industry standard of providing limited "samples," including ones of Zymaxid®, as it sought to convert all Zymar® patients to Zymaxid®.

373. This announcement was reinforced at the June 21, 2010, Allergan National Sales Meeting in Memphis, Tennessee, which Relator Wood attended. There, Allergan's Vice President of Sales, Joseph Schultz elaborated on Allergan's discontinuance of free drug shipments. Also in attendance at this meeting were Zymaxid® Product Manager Luke Greenwalt, Relator Wood's manager Jon Weidner, and sales representatives Kimberly Mautte, Phillip Edmonson, Kim Johnson, Scott Meredith, Farley Dillinger, Kate Bergan, and Alison Grumet.

374. At the Zymaxid® Breakout Workshops, the sales force, including Relator Wood, was trained on, and practiced role plays to (1) inform doctors of Allergan's abrupt discontinuation of providing free drugs, including Pred Forte® samples; (2) anticipate and

counter strong objections to the same; and (3) convince cataract surgeons to begin prescribing Zymaxid® rather than soon-to-be generic Zymar® for prevention of endophthalmitis.

375. Allergan did not, however, change its practice of providing free customized prescription pads and patient instruction sheets. In addition, Allergan continued its policy of providing free or reduced-cost consulting services and reimbursement assistance to induce prescriptions of its eye care drugs, including Restasis®.

376. On Monday, January 17, 2011, Allergan informed its sales representatives that they would no longer be sampling, detailing, or supporting Pred Forte®, Acuvail®, and Zymaxid®, and would no longer be paid a bonus or commission on these products. Allergan explained to its sales force that the promotion was "not profitable," and claimed that, after paying for royalties, samples, rebates, and JG Pads printing, the net profit was no longer worth the investment in resources or time. That admission signals both the centrality and effectiveness of Allergan's illegal provision of CCKs and mass quantities of drugs to its overall promotional strategy — that is, it was only the provision of inducements to physicians that made promotion of Acuvail® and Zymaxid®, and before them Acular LS® and Zymar®, profitable.

XII. ALLERGAN FALSELY CERTIFIES ITS COMPLAINCE WITH CALIFORNIA HEALTH AND SAFETY CODE SECTIONS 119400 AND 119402

377. Despite its adoption of a compliance program, since 2005, Allergan has falsely certified its compliance with the State of California's "Comprehensive Compliance Program," which requires an effective compliance program, as required by the PhRMA Code, and California Health and Safety Code §§ 119400 and 119402.

378. Allergan has publicly represented that it is committed to establishing and maintaining a comprehensive and effective compliance program in accordance with California

Health and Safety Code §§ 119400 and 119402 and the "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "HHS-OIG Guidance"). Allergan has misleadingly boasted that its U.S. Healthcare Law Compliance Program is one of the key components of its commitment to the highest standards of corporate conduct.

379. Allergan's California Health and Safety Code compliance declarations falsely stated that on or before July 1, 2005, Allergan had managed its operations and dealings with California medical or health professionals in compliance with its Comprehensive Compliance Program and California Health and Safety Code §§ 119400 and 119402.

380. Allergan's declarations of compliance have been misleading and deceptive in certifying that Allergan was not aware of any violations of its Comprehensive Compliance Program relating to California medical or health professionals on or after 2005 "that have not been addressed and corrective action taken." Allergan's declaration is an admission that it had not been in compliance, as it had needed to address "violations" requiring "corrective action."

381. Allergan's also artfully drafted its 2010 re-certification of compliance to foist blame for compliance violations onto its employees. Allergan's claim that rogue employees bore responsibility for compliance violations was untrue: as described in this Second Amended Complaint, Allergan's senior management itself designed and instructed sales representatives to implement the Fraudulent Kickback and Marketing Schemes. Nonetheless, Allergan's certification expressly blames its employees for any violations, while concealing management's responsibility for the fraudulent schemes, which the Company only began to modify in late 2008:

> "By making this declaration, Allergan is not asserting that in all circumstances it can prevent individual employees from conduct that deviates from its policies. Allergan expects employees to

> comply with its Comprehensive Compliance Program and has made a good faith effort to enforce its Comprehensive Compliance Program, prevent violations, and address any inappropriate conduct that may occur."

382. Allergan's certification of compliance with California Health and Safety Code §§ 119400 and 119402 was false, misleading, and intended to cover up Allergan's corporate-wide policies as described in this Second Amended Complaint. That false and misleading certification caused the State of California to pay or reimburse for Allergan's drug products, which were otherwise ineligible for payment or reimbursement.

XIII. ALLERGAN'S FRAUDULENT KICKBACK SCHEME VIOLATED ALLERGAN'S OBLIGATIONS UNDER THE MEDICAID BEST PRICE STATUTE

383. As described above, Allergan's Fraudulent Kickback Scheme resulted in the provision of multiple free Allergan drug products through its CCK program and Sample Shipment Agreements. These were not "samples" provided to educate ophthalmologists on the use of drug products, as contemplated by the Prescription Drug Marketing Act. Rather, Allergan supplied ophthalmologists with large shipments of its drug products, intending that these shipments would induce ophthalmologists to prescribe more or different Allergan products to their patients. These large shipments included 5 ml "trade-size" bottles and large orders of 1 ml bottles of Acular®, Acular LS®, Acuvail®, Zymar®, Pred Forte®, Optive® and Refresh® brand products, which were sent directly to ophthalmologists during the relevant time periods alleged herein, contingent on the ophthalmologists' prescribing of additional Allergan drug products.

384. Despite the large size of these shipments of Allergan drug products (which Allergan referred to as "samples"), ophthalmologists were never billed or invoiced for these products.

385. Not only did Allergan provide samples to induce sales, for certain of its "high prescribers," as described herein, Allergan provided free trade-size bottles of its drug products, which were sufficient to treat cataract patients for their entire regimen of care. As such, these trade sizes were hardly intended to allow the doctor and patient to "try out" the Allergan products; rather, they were "free goods" and were clearly intended to induce the prescribing of other Allergan drug products.

386. Allergan's Fraudulent Kickback Scheme was a multi-faceted marketing program that supplied large shipments of free drugs (along with free shipping), free physician supplies, and free practice management consulting services to Allergan's physician, surgery center, and hospital customers.

387. But for Allergan's provision of free drugs, supplies, and services, Allergan's customers would have purchased at least some of these drugs, supplies, and services. The free drugs were thus a discount or price concession on the Allergan drugs which were intended to (and did) induce prescribing of the Allergan drug products, and/or were contingent on future discounts.

388. Cataract surgeons use Allergan's Zymar® in different ways, as it may be administered pre-operatively, peri-operatively, and/or post-operatively. During the relevant time period, Zymar was used or was made available for use during cataract surgeries. For example, certain physician customers requested from Relator to have Zymar 5 ml samples on hand to keep

in the operating room at their respective ambulatory surgery centers. These surgery centers include Cleveland Eye Clinic, Brecksville Surgery Center, and Lippy Surgery Center.

389. The precise drugs that Allergan provided as part of its inducement scheme, as well as which prescriptions it received in return, varied from practitioner to practitioner. The constant among all the various iterations of inducements and prescriptions written in exchange for those inducements was just that: they were all inducements, and as such, Allergan's provision of free drugs was always contingent on the recipient's agreement to write concomitant prescriptions for Allergan drug products. The following were common scenarios, although not the only scenarios, of drugs that Allergan provided and the prescriptions that were written in return:

a. Allergan provided free Pred Forte® (10 ml) and Acular LS® (1 ml), contingent on the health care professional writing prescriptions for Acular LS® (5 ml) and Zymar® (5 ml). The overall course of treatment in this scenario would entail pre-operative use of Zymar® for three days, as well as post-operative use of Pred Forte® for two to four weeks, Acular LS® for one to four weeks, and Zymar® for seven days.

b. Allergan provided free Pred Forte® (10 ml) and Acular LS® (5 ml), contingent on the health care professional writing a prescription for Zymar® (5 ml). The overall course of treatment in this scenario would entail pre-operative use of Zymar® for three days, as well as post-operative use of Pred Forte® for two to four weeks, Acular LS® for two to four weeks, and Zymar® for seven days.

c. Allergan provided free Pred Forte® (10ml) and Zymar® (5 ml), contingent on the health care professional writing a prescription for Acuvail® (30 single-use vials, 0.4 ml each). The overall course of treatment in this scenario would entail pre-operative use of Zymar® for three days, as well as post-operative use of Pred Forte® for two to four weeks, Acuvail® for two to four weeks, and Zymar® for seven days. After introducing Acuvail® to replace Acular LS®, Allergan changed its provision of drugs to Dr. Paul Turgeon (Eye Centers of Ohio, Canton, Ohio) from scenario (b) to scenario (c). While Dr. Turgeon continued to receive inducements from Allergan to prescribe its drugs, under the new arrangement, he received free Zymar® instead of Acular LS®, and in exchange prescribed Acuvail® instead of Zymar®.

d. Allergan provided free Pred Forte® (5 ml) and Acular LS® (1 ml), contingent on the health care professional writing prescriptions for Acular LS® (5 ml) and Zymar® (5 ml). The overall course of treatment in this scenario would entail pre-operative use of Zymar® for three days, as well as post-operative use of Pred Forte® for two to four weeks, Acular LS® for two to four weeks, and Zymar® for seven days. Dr. Richard Lehrer (Ohio Eye Alliance, Canton and Alliance, Ohio) received this regimen. Dr. Lehrer, who split his prescriptions evenly between Allergan and Alcon products, preferred the 5 ml rather than 10 ml size of Pred Forte®, because he believed it prevented patients from using too much. The 1 ml samples

of Acular LS® were given to some patients immediately after surgery in the Alliance surgery center, as were samples of Zymar® on occasion.

e. Allergan provided free Pred Forte® (10 ml) and Acular LS® (1 ml), continent on the health care professional writing prescriptions for Acular LS® (5 ml) and Zymar® (5 ml). The overall course of treatment in this scenario would entail pre-operative use of Zymar® for three days, as well as post-operative use of Pred Forte® for two to four weeks, Acular LS® for two to four weeks, and Zymar® for seven days. This was the most common scenario, and notable participants included Drs. William Wiley, Shamik Bafna, and Thomas Chester of the Cleveland Eye Clinic (multiple locations in Ohio) and Dr. Zafar Sheik of Warren Ophthalmology, Warren, Ohio. The ophthalmologists occasionally used Zymar® intraoperatively and frequently requested, and were provided with, samples of Zymar® (5 ml) to keep in the operating rooms of their ambulatory surgery centers (Brecksville Surgery Center for the Cleveland Eye Clinic, and the Lippy Surgery Center for Warren Ophthalmology). In one instance, Lilly Surgery Center called Relator Wood to request 5 ml samples of Zymar® for intraoperative use. After obtaining the physician's signature at the clinic, Relator delivered the samples to the surgery center, where members of the staff asked him how they could purchase Zymar® directly from Allergan, so they would not have to be entirely reliant on the samples from Allergan. Area Manager Jon Weidner instructed Relator to

continue providing Zymar® samples to the surgery center instead of informing them how to purchase the drug directly.

f. Allergan provided free Pred Forte® (10 ml), Zymar® (1 ml), and Acuvail® (5 single-use vials, 0.4 ml each), contingent on the health care professional writing a prescription for Zymar® (5 ml). The overall course of treatment in this scenario would entail pre-operative use of Zymar® for three days, as well as post-operative use of Pred Forte® for two to four weeks, Zymar® for seven days, and Acuvail® for seven days (only in high-risk patients or those for which it was otherwise necessary). Drs. Wang, Yakubov, Aey, Wilson, and Erzurum of Eye Care Associates (Youngstown, Ohio) participated in this scenario. Eye Care Associates had previously prescribed Alcon's Vigamox® in exchange for free samples of Omnipred® (10 ml), but decided to begin prescribing Zymar® after Alcon ceased providing free samples of Omnipred® in April 2010. The inducements provided by Allergan precisely mirrored those that had previously been provided by Alcon.

390. As the above bundling examples illustrate, Allergan knew and expected that a substantial number of the prescriptions written by ophthalmologists for Allergan products was the direct result of Allergan's Fraudulent Kickback Scheme.

391. According to the Medicaid national rebate agreement, of which Allergan is a signatory, Average Manufacturer Price ("AMP") must include the free samples that Allergan provided contingent on the prescribing of additional Allergan drugs. AMP is calculated as "Net Sales divided by the number of units sold, excluding free goods (i.e., drugs or any other items

given away, but not contingent on any purchase requirements)." *See* Medicaid Sample Rebate Agreement at 1, *available at* https://www.cms.gov/MedicaidDrugRebateProgram/downloads /rebateagreement.pdf (emphasis added).

392. The reality of the nature of the work of Allergan's territory managers, as it has been carried out for decades, is that the relevant "purchasers" are not the end-users (i.e., the patients) of Allergan's drugs but, rather, the prescribing physicians on whom the Allergan territory managers call. That is because the patient is not at liberty to choose personally which prescription pharmaceutical he or she desires. As such, the patient cannot be fairly characterized as the "buyer." Instead, it is patient's physician, who is vested with both a moral and legal duty to prescribe medication appropriately, who selects the medication and is the appropriate focus of the sales promotion. The "sale" of Allergan's drug products is thus the exchange of non-binding commitments between the Allergan territory manager and the physician at the end of each successful call. Through such commitments, Allergan will provide its products (induced through ample kickbacks described herein) and the doctor will then prescribe; for all practical purposes, this is a sale.

393. Allergan has itself explicitly recognized that its customer is the physician. In the PowerPoint presentation, titled "2009 External Disease Update," which announced the discontinuation of CCKs to the entire ophthalmology sales force, Allergan continually referred to physicians as its customers — e.g., "[w]e will sell the Patient Care Kits … to our customers for fair market value," "[c]ustomers will have the opportunity to choose from two kit configurations," "[a] customer can now go online directly at GJ Pads to personally design their Patient Instruction Sheets." In context, each of the preceding statements plainly refers to the physician.

394. Because Allergan appreciated who the "real" buyer has been, it structured its sales force and its marketing tactics to accommodate this unique sales environment. When an Allergan territory manager details a doctor, he or she attempts to obtain the absolute maximum commitment from his or her "buyer"—a non-binding commitment from the ophthalmologist to prescribe one of Allergan's assigned products.

395. Allergan thus promoted its drugs for sale to health care professionals, and provided abundant quantities of free samples to induce such sales.

396. Allergan's calculation of the AMP for the "sale" of these drugs to health care professionals, which omitted its free drugs contingent on prescribing additional Allergan drugs, and which Allergan reported to Medicaid, was false. Section 1927(c)(1)(C)(ii)(I) of the Social Security Act specifies that Best Price must include free goods that are contingent on any purchase requirement. Thus, only those free goods that are not contingent on any purchase requirements may be excluded from Best Price.

397. Allergan's provision of free products contingent on sales to ophthalmologists should have been reported as the new Best Price on Zymar®, Acular LS®, Pred Forte®, Acular, Acuvail®, and Optive® and Refresh® brand eye drops. Based upon available Medicaid payment records, Medicaid did not receive Allergan's Best Price, which Allergan was required to report to Medicaid, but did not.

398. Pursuant to the Best Price Agreement, the "Best Price" Allergan was obligated to report should have been "inclusive of cash discounts, free goods, volume discounts, and rebates. . . . ." Allergan was obligated to adjust the "Best Price" "if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized." As such, Allergan was obligated to report the "free goods" alleged herein, which it did not.

399. Since it began in 1990, the Best Price reporting system has essentially operated as an honor system, under which manufacturers like Allergan are trusted to report their accurate Best Prices on a quarterly basis and then pay the states the correct Medicaid rebates. From the outset, CMS conducted only limited checks for reporting errors in manufacturer-reported drug prices and only reviewed price-determination methods when manufacturers requested recalculations of prior rebates. Allergan was thus on its honor to fairly report Best Price and AMP consistent with the law and the rebate agreements it had entered into with the Government.

400. At all times material hereto, Allergan had active Medicaid rebate agreements. Allergan's Medicaid rebate labeler codes under the Best Price Program were 00023 and 11980.

401. At all material times hereto, Allergan participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Drug Rebate Program, pursuant to its rebate agreement with HCFA, now known as the Centers for Medicare and Medicaid Services ("CMS"), its drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A), 1396d(a)(12), and 1396r-8(a)(l). Under the Medicaid Drug Rebate Program and its rebate agreement with HCFA, Allergan generally agreed: (i) to report quarterly to HCFA its true AMP and, for single source and innovator multiple source drugs, the "Best Price" for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(l)(C); and (ii) to pay quarterly accurate rebates to each state based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and "Best Price," or a minimum

rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(l).

402. At all material times, Allergan participated in the 340B Program, 42 U.S.C. § 256b, which is part of the Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300gg-92. Under the 340B Program and their agreements with HHS, Allergan generally agreed that the amount that it required the "covered entities," as set forth under § 340B(a)(4) of the PHS Act, to pay for drug products would not exceed the AMP, as reported to HCFA in the previous calendar quarter, minus a specified rebate percentage that was derived in part from the Medicaid rebate paid by Allergan in the preceding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a).

403. Medicaid's reimbursements of the Allergan free drug products provided to ophthalmologists during the relevant period were as follows:

A. Zymar®: From 2003-2009, Medicaid paid $38,437,801.73. Unit prices ranged as follows: $8.01 to $14.30. (The Unit Price figures do not include several outlier quarters where the data seems to be incorrect (i.e., the 3rd quarter of 2006 where the Unit Price of Zymar® is $215.52)

B. Acular LS®: From 2004-2009, Medicaid paid $32,473,608.41. Unit prices ranged as follows: $10.59 to $20.88.

C. Acular®: From 2003-2007, Medicaid paid $59,967,789.35. Unit prices ranged as follows: $10.28 to $20.72.

D. Acuvail®: Since® Acuvail was approved in July of 2009, the CMS website only lists Medicaid sales for Q3 and Q4 of 2009. Total Medicaid Reimbursements for 2009 (Q3-Q4): $28,500.36. Unit price was $5.17.

E. Pred-Forte®: From 2003-2009, Medicaid paid $2,334,052.50. Unit prices ranged as follows: $3.10 to $4.78.

F. Optive®: From 2007-2009, Medicaid paid $ 132,643.98. Unit prices ranges as follows: $0.32 to $0.64.

G. Refresh®: From 2005-2009, Medicaid paid $1,167,711.61 (Figure does not include the 3rd quarter of 2006, which looks to be outlier information). Unit prices ranges as follows: $0.31 to $0.36.

H. Refresh Plus®: From 2005-2009, Medicaid paid $1,280,532.66. Unit prices ranged as follows: $0.26 to $0.44.

I. Refresh Tears®: From 2006-2009, Medicaid paid $1,411,581.28. Unit prices ranged as follows: $0.37 to $0.52.

J. Refresh PM®: From 2005-2009, Medicaid paid $439,548.18. Unit prices ranged as follows: $1.85 to $2.54.

Relator Wood has provided the Government with full tables for each drug for each available quarter during the relevant time period.

404. Medicaid thus did not receive the Best Price (i.e., the "free goods" price) that Allergan was providing to ophthalmologists. Allergan knowingly (or with reckless disregard for the truth) made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government. Specifically, for each quarter noted above, and continuing through the present, Allergan knowingly (or in reckless disregard of the truth) submitted false quarterly statements to CMS of its Best Prices on the Allergan products to reduce improperly its rebate obligations to the States under the Best Price Program. Allergan's false quarterly statements of its Best Prices caused the States to submit false and inflated

submissions to the Federal Government for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2), (a)(7).

405. Allergan was required to certify its compliance with applicable law, including the Medicaid Rebate program. Allergan's knowing failure to comply renders its certifications false, either expressly or impliedly.

406. The false reports of Best Price by Allergan trigger liability under the FCA and its state counterparts. Under the Best Price statute, Allergan was to report its truthful prices to the Secretary, who in turn reported these prices to the states, who then invoiced Allergan the amount of Best Price rebates that were owing. Under the FCA and the State *Qui Tam* counterparts, Allergan is liable even if it did not make a false statement itself directly to the state "Medicaid agency," so long as a direct or indirect result of its conduct was causing a false statement to be made to the state Medicaid agency.

407. Because Allergan knowingly, and in reckless disregard for the truth, made false reports of Best Price or the AMP to the Secretary, then the "unit rebate amounts" or "URAs," which represent the products of calculations performed on AMP's and Best Prices which were Allergan's responsibility to report, were also false. As such, (1) Allergan knowingly, and in reckless disregard for the truth, made, used, or caused to be used Best Price or AMP statements or records made to CMS to conceal, avoid, or decrease an obligation to the United States; (2) the statements or records were false; and (3) Allergan knew that the statements or records were false.

408. By virtue of the false or fraudulent claims that Allergan knowingly caused to be presented, the United States and the *Qui Tam* States have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

XIV. ALLERGAN'S FRAUDULENT KICKBACK SCHEME VIOLATED THE STARK LAW

409. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn *et seq.*, known as the "Stark Law," prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicare or Medicaid patients to the manufacturer for certain "designated health services," including outpatient prescription drugs, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6).

410. Allergan's financial relationships included written contracts with referring physicians to provide free shipments of CCKs, written contracts with referring physicians to provide Allergan drug shipments, agreements with referring physicians to provide ECBA consulting services, and agreements with referring physicians to provide Allergan *Access*®, all at no charge.

411. Allergan's conduct as described in this Second Amended Complaint repeatedly violated the Stark Law, which in turn resulted in violations of the False Claims Act, because Allergan's unlawful remuneration and services to prescribing physicians with which it had a financial relationship induced those physicians to prescribe Allergan's drug products.

412. The Stark Law provides that Allergan shall not cause to be presented a Medicare or Medicaid claim for prescriptions in violation of the Stark Law. The Stark Law also prohibits payment of claims for prescriptions rendered in violation of its provisions. 42 U.S.C. §1395nn(a)(1), (g)(1). Thus all Medicare and Medicaid payment of claims for prescriptions tainted by Allergan's Stark Law violations were ineligible for payment.

413. In addition, Allergan's conduct as described in this Second Amended Complaint caused health care providers, including pharmacies and PDPs, to falsely certify compliance with the Stark Law, in violation of the False Claims Act.

XV. ALLERGAN'S RETALIATION AGAINST RELATOR WOOD

414. On July 6, 2010, Allergan terminated Relator Wood's employment in retaliation for his whistle-blowing activities. Prior to July 6, 2010, Relator Wood received favorable performance reviews, and had never been subject to any disciplinary action. Rather than act on Relator Wood's reports of compliance violations, Allergan chose to use Relator Wood as a scapegoat to cover Allergan's long-standing illegal conduct.

415. Relator Wood's termination was a direct result of Allergan corporate policies that valued profits over lawful behavior. In accordance with these policies, in April 2010, Relator Wood prepared a written proposal, embodied in a simple informal term sheet, for Novus Clinic, a group of ophthalmologists, in order to win back Novus' business from rival Alcon, since Alcon was discontinuing its free provision of the topical steroid Omnipred®. The written term sheet was similar in form to term sheets that Relator Wood had prepared in the past, that other Allergan sales representatives had prepared, and that Relator Wood's own managers had approved. Allergan would later refer to Relator Wood's proposal as a "home-made sales piece."

416. The Novus Clinic proposal included terms that were entirely consistent with existing Allergan policy that fostered and condoned the Fraudulent Marketing and Fraudulent Kickback Schemes. As to the Fraudulent Marketing Scheme, the proposal included the promotion of Zymaxid® for off-label use in cataract surgeries. As to the Fraudulent Kickback Scheme, the the term sheet proposed that for every Zymar® prescription Novus would write, it

would receive a free 10 ml bottle of Pred Forte® and a free 1 ml bottle of Zymar®, in addition to a supply of pre-printed Zymar® prescription pads.

417. Relator Wood's Area Manager, Jon Weidner, had previously approved similar verbiage related to the distribution of free Allergan drugs, and was present for many negotiations of these terms with ophthalmology clinics, similar to the negotiations with the Novus Clinic. As such, Relator Wood was only doing what his manager had in the past encouraged and approved.

418. Shortly after giving the proposal to Novus Clinic, Relator Wood was notified that an Alcon sales representative had lodged a complaint against him, based on this offer to provide free drugs to Novus Clinic. Alcon had itself only ceased using free drugs to induce physicians to prescribe its ophthalmic drugs in conjunction with cataract surgery in January 2010, and the Alcon sales representative's complaint was likely promoted by the recognition that, without being able match Allergan's offers of kickbacks to physicians, he was placed at a competitive disadvantage.

419. Relator Wood was summoned to attend conference call on June 15, 2010, with three Allergan lawyers: Damon Burrows, Kimberly Denham, and Ryan Brown. During this call, Relator Wood was asked questions about the Novus proposal. Relator Wood responded that he had merely prepared a summary proposal for Novus Clinic, that the proposal was entirely consistent with Allergan's schemes to "win" business, and that he was only following company policy, including directions he had been given by his manager Jon Weidner and others.

420. The next day, June 16, 2010, during a field ride with his Area Manager, Jon Weidner, Relator Wood discussed the conference call where he was summoned to discuss the Novus Clinic proposal. Relator Wood then showed Weidner the Novus Clinic proposal sheet. Weidner responded that the sheet did not look like a home-made sales piece, but rather looked

like a summary of Relator Wood's discussions with Novus Clinic to promote Allergan products, and was in line with Allergan's long-standing business practices. According to Weidner, Relator Wood's only mistake was to put the Allergan proposal in writing and in an email. As such, Weidner predicted that Relator Wood would only receive a written warning from Allergan.

421. Relator Wood later obtained information that a sales representative in Salt Lake City, Utah, Matt Nielsen, had also been accused of creating a "home-made sales piece." Nielsen was apparently fired by Allergan (along with his manager, who was also fired), but was offered "hush" money by Allergan due to the fact that he had a recorded voice mail from his manager directing him to engage in this practice. Nielsen also apparently provided Allergan's Human Resources and Compliance Departments with documents that evidenced Allergan's illegal and fraudulent schemes.

422. Allergan's continuing policy of bribing ophthalmologists, while rival Alcon had only recently discontinued the same policy, created an environment in which its principal competitor could accuse Allergan sales representatives of violating the law, though they were only following their managers' instructions. Relator Wood was thus unfairly caught in middle of the Allergan-Alcon competition and Allergan's own illegal practices. These illegal practices were the subject of considerable spin by Allergan trainers. Notably, Allergan misled Relator Wood and its sales force into believing that providing the free kickbacks to physicians described in this complaint was lawful, as long as the sales representatives themselves believed that it benefitted the patient.

423. Allergan thus unfairly singled out Relator Wood as a scapegoat to use as an excuse to cover up its own widespread, unlawful conduct.

424. Allergan's written compliance rules encourage employees to express any concerns that they may have about certain Allergan practices without fear of retaliation. In reliance on this purported protection, Relator Wood reported his concerns about the illegal sampling and kickback scheme to Allergan's Compliance Department, as well as to the company's Human Resources department.

425. Prior to his termination on July 6, 2010, Relator Wood relied upon Allergan's reporting policy and provided the aforementioned Allergan personnel with specific information regarding sampling directives and activities that he believed, in good faith, were in violation of Allergan's policies and federal law insofar as the company had for many years (i) provided inducements to health care professionals with the intent to influence these persons to recommend or purchase health care products that may be reimbursed by a federal health care program; (ii) provided something to health care professionals in exchange for any implicit or explicit agreement or understanding to use, purchase, order, recommend, prescribe or dispense any Allergan product; and (iii) improperly used prescription drug samples other than in response to a licensed practitioner's written request.

426. In response to his complaints, on July 6, 2010, Relator Wood's supervisors retaliated against him by terminating his employment.

427. It is no coincidence that Relator Wood was terminated just after he internally reported his managers and other personnel for violating company policy and federal laws relating to illegal sampling and kickbacks.

428. Plainly, Allergan sought to (and did) intimidate, punish, and retaliate against Relator Wood for his lawful and proper decision to follow company policy and report what he (accurately) considered to be illegal directions and activities by his supervisors and Allergan. As

such, the company improperly retaliated against Relator Wood as a result of his whistle-blowing activity.

429. As a direct result of Allergan's unlawful retaliation, Relator Wood has suffered, and continues to suffer, severe emotional distress.

430. Relator Wood was discharged, threatened, harassed, and discriminated against by Allergan because of his lawful acts in investigating and reporting compliance violations. As such, Relator Wood is entitled to reinstatement, two times the amount of his back pay, interest on the back pay, and compensation for all damages allowed by law, including but not limited to special damages, and damages for emotional distress, sustained as a result of his unlawful termination.

COUNT I
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A))[1]

431. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

432. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval for the Allergan drugs, in violation of 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A).

433. As a result of Defendant's actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

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[1] To the extent wrongdoing occurred after May 20, 2009, the Second Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B))[2]

434. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

435. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).

436. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid and may continue to be paying or reimbursing for the Allergan drugs, including Zymar® prescribed to patients enrolled in Federal Programs.

437. As a result of Defendant's actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C))[3]

438. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

439. As detailed above, Defendant knowingly conspired, and may still be conspiring, with the various health care professionals identified and described herein (as well as other

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[2] To the extent wrongdoing occurred after May 20, 2009, the Second Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.
[3] To the extent wrongdoing occurred after May 20, 2009, the Second Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

unnamed co-conspirators) to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). Defendant and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

440. As a result of Defendant's actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(7); 31 U.S.C. § 3729(a)(1)(G))[4]

441. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

442. As alleged in detail above, Allergan knowingly avoided or decreased its obligation to pay or transmit money to the Government. Specifically, Allergan: (i) made, used, or caused to made or used, a record or statement to conceal, avoid, or decrease an obligation to the United States; (ii) the records or statements were in fact false; and (iii) it knew that the records or statements were false.

443. As a result of Defendant's actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT V
(Violation of False Claims Act, 31 U.S.C. § 3730(h))

444. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

445. As a result of Relator's lawful acts in furtherance of protected activities in the investigation and reporting of fraud, Defendant retaliated against Relator.

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[4] To the extent wrongdoing occurred after May 20, 2009, the Second Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

446. Relator's termination of employment was a direct result of Defendant's retaliatory acts, causing Relator to suffer, and continue to suffer, substantial financial and emotional damage in an amount to be proven at trial.

COUNT VI
(Violation of California False Claims Act)

447. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

448. This is a civil action brought by Relator, on behalf of the State of California, against Defendant under the California False Claims Act, Cal. Gov't Code § 12652(c).

449. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

450. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

451. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of California, or its political subdivisions, in violation of Cal. Gov't Code § 12651(a)(7).

452. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

453. As a result of Defendant's actions, as set forth above, the State of California and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VII
(Violation of Colorado Medicaid False Claims Act)

454. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

455. This is a civil action brought by Relator, on behalf of the State of Colorado, against Defendant under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306(2).

456. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

457. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

458. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

459. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

460. As a result of Defendant's actions, as set forth above, the State of Colorado and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VIII
(Violation of Connecticut False Claims Act)

461. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

462. This is a civil action brought by Relator, on behalf of the State of Connecticut, against Defendant under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301d.

463. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Connecticut, or its political subdivisions, false or fraudulent claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(1).

464. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(2).

465. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut, or its political subdivisions, under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(7).

466. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-

related management services for recipients of state and state subdivision funded health insurance programs.

467. As a result of Defendant's actions, as set forth above, the State of Connecticut and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT IX
(Violation of Delaware False Claims and Reporting Act)

468. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

469. This is a civil action brought by of Relator, on behalf of the State of Delaware, against Defendant under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1203(b).

470. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

471. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

472. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

473. The State of Delaware, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the State of Delaware.

474. As a result of Defendant's actions, as set forth above, the State of Delaware and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT X
(Violation of District of Columbia False Claims Act)

475. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

476. This is a civil action brought by Relator, on behalf of the District of Columbia, against Defendant under the District of Columbia False Claims Act, D.C. Code § 2-308.15(b).

477. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.14(a)(1).

478. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(2).

479. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(7).

480. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

481. As a result of Defendant's actions, as set forth above, the District of Columbia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XI
(Violation of Florida False Claims Act)

482. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

483. This is a civil action brought by Relator, on behalf of the State of Florida, against Defendant under the Florida False Claims Act, Fla. Stat. § 68.083(2).

484. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

485. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

486. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

487. The State of Florida, or its agencies, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

488. As a result of Defendant's actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT XII
(Violation of Georgia False Medicaid Claims Act)

489. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

490. This is a civil action brought by Relator, on behalf of the State of Georgia, against Defendant pursuant to the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).

491. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

492. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

493. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

494. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

495. As a result of Defendant's actions, as set forth above, the State of Georgia and/or political subdivisions have been, and may continue to be, severely damaged.

COUNT XIII
(Violation of Hawaii False Claims Act)

496. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

497. This is a civil action brought by Relator, on behalf of the State of Hawaii, against Defendant under the Hawaii False Claim Act, Haw. Rev. Stat. § 661-25.

498. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

499. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).

500. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).

501. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

502. As a result of Defendant's actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIV
(Violation of Illinois False Claims Whistleblower Reward and Protection Act)

503. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

504. This is a civil action brought by Relator, on behalf of the State of Illinois, against Defendant under the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/4(b).

505. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an

officer or employee of the State of Illinois, or a member of the Illinois National Guard, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

506. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false record or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

507. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

508. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

509. As a result of Defendant's actions, as set forth above, the State of Illinois and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XV
(Violation of Indiana False Claims and Whistleblower Protection Act)

510. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

511. This is a civil action brought by Relator, on behalf of the State of Indiana, against Defendant under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-4(a).

512. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).

513. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

514. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit

money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

515. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

516. As a result of Defendant's actions, as set forth above, the State of Indiana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI
(Violation of Louisiana Medical Assistance Programs Integrity Law)

517. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

518. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs, against Defendant under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.

519. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

520. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or

attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

521. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of La. Rev. Stat. Ann. § 46:438.3(D).

522. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendant, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendant's claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

523. As a result of Defendant's actions, as set forth above, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XVII
(Violation of Maryland False Health Claims Act)

524. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

525. This is a civil action brought by Relator, on behalf of the State of Maryland, against Defendant under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-604.

526. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

527. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

528. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still me making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

529. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

530. As a result of Defendant's actions, as set forth above, the State of Maryland and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
(Violation of Massachusetts False Claims Act)

531. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

532. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendant under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5C(2).

533. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

534. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

535. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

536. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

537. As a result of Defendant's actions, as set forth above, the Commonwealth of Massachusetts and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
(Violation of Michigan Medicaid False Claims Act)

538. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

539. This is a civil action brought by Relator, on behalf of the State of Michigan, against Defendant under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.610a(1).

540. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or false representations of material facts in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

541. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made or caused to be made false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

542. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit, or the initial or continued right of any other person on whose behalf Defendant has applied for or is receiving a benefit with intent to obtain a benefit to which Defendant were not entitled or in an amount greater than that to which Defendant were entitled, in violation of Mich. Comp. Laws § 400.603(3).

543. Defendant, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly made, presented or caused to be made or presented, and may still be presenting or causing to be presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

544. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

545. As a result of Defendant's actions, as set forth above, the State of Michigan and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
(Violation of Minnesota False Claims Act)

546. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

547. This is a civil action brought by Relator, on behalf of the State of Minnesota, against Defendant under the Minnesota False Claims Act, Minn. Stat. § 15C.05(a).

548. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

549. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claim paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

550. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

551. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

552. As a result of Defendant's actions, as set forth above, the State of Minnesota and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI
(Violation of Montana False Claims Act)

553. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

554. This is a civil action brought by Relator, on behalf of the State of Montana against, Defendant under the Montana False Claims Act, Mont. Code Ann. § 17-8-406(1).

555. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

556. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

557. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).

558. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

559. As a result of Defendant's actions, as set forth above, the State of Montana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXII
(Violation of Nevada False Claims Act)

560. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

561. This is a civil action brought by Relator, on behalf of the State of Nevada, against Defendant under the Nevada False Claims Act, Nev. Rev. Stat. § 357.080(1).

562. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

563. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

564. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada, or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

565. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

566. As a result of Defendant's actions, as set forth above, the State of Nevada and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
(Violation of New Jersey False Claims Act)

567. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

568. This is a civil action brought by Relator, on behalf of the State of New Jersey, against Defendant pursuant to the New Jersey Fraud False Claims Act, N.J. Stat. Ann. § 2A:32C-5(b).

569. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

570. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

571. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

572. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

573. As a result of Defendant's actions, as set forth above, the State of New Jersey and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
(Violation of New Mexico Medicaid False Claims Act)

574. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

575. This is a civil action brought by Relator, on behalf of the State of New Mexico, against Defendant under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-7(B).

576. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).

577. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).

578. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico, or its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E).

579. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

580. As a result of Defendant's actions, as set forth above, the State of New Mexico and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXV
(Violation of New York False Claims Act)

581. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

582. This is a civil action brought by Relator, on behalf of the State of New York, against Defendant under the New York False Claims Act, N.Y. State Fin. Law § 190(2).

583. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an

officer, employee or agent of the State of New York, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

584. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved by the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(b).

585. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

586. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

587. As a result of Defendant's actions, set forth above, the State of New York and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVI
(Violation of North Carolina False Claims Act)

588. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

589. This is a civil action brought by Relator, on behalf of the State of North Carolina, against Defendant under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).

590. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

591. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

592. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina, or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

593. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

594. As a result of Defendant's actions, as set forth above, the State of North Carolina and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVII
(Violation of Oklahoma Medicaid False Claims Act)

595. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

596. This is a civil action brought by Relator, on behalf of the State of Oklahoma, against Defendant pursuant to the Oklahoma Medicaid Fraud False Claims Act, Okla. Stat. tit. 63, § 5053.2(B)(1).

597. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

598. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

599. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

600. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

601. As a result of Defendant's actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVIII
(Violation of Rhode Island False Claims Act)

602. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

603. This is a civil action brought by Relator, on behalf of the State of Rhode Island, against Defendant pursuant to the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).

604. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Rhode Island or a member of Rhode Island's National Guard,

false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

605. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

606. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

607. The State of Rhode Island, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

608. As a result of Defendant's actions, as set forth above, the State of Rhode Island and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIX
(Violation of Tennessee Medicaid False Claims Act)

609. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

610. This is a civil action brought by Relator, on behalf of the State of Tennessee, against Defendant under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b).

611. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program,, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

612. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

613. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

614. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

615. As a result of Defendant's actions, as set forth above, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXX
(Violation of Texas Medicaid Fraud Prevention Act)

616. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

617. This is a civil action brought by Relator, on behalf of the State of Texas against, Defendant under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.101(a).

618. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or misrepresentations of material fact that permitted Defendant to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

619. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed — and may still be concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendant to receive a benefit or payment under the Medicaid program that was not

authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

620. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

621. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and may still be making, claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

622. The State of Texas, or it political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

623. As a result of Defendant's actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXI
(Violation of Virginia Fraud Against Taxpayers Act)

624. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

625. This is a civil action brought by Relator, on behalf of the Commonwealth of Virginia, against Defendant under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).

626. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

627. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

628. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

629. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

630. As a result of Defendant's actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXII
(Violation of Wisconsin False Claims for Medical Assistance Law)

631. Relator incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

632. This is a civil action brought by Relator, on behalf of the State of Wisconsin, against Defendant under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(5)(a).

633. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the State of Wisconsin, or its political subdivisions, false or fraudulent claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(a).

634. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain approval or payment of false claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(b).

635. The State of Wisconsin, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

636. As a result of Defendant's actions, as set forth above, the State of Wisconsin and/or its political subdivisions have been, and may continue to be, severely damaged.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendant as follows:

A. That Defendant be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729 *et seq.*; Cal. Gov't Code § 12650 *et seq.*; Colo. Rev. Stat. § 25.5-4-304 *et seq.*; Conn. Gen. Stat. § 17b-301a *et seq.*; Del. Code Ann. tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.13 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Ga. Code Ann. § 49-4-168 *et seq.*; Haw. Rev. Stat. § 661-21 *et seq.*; 740 Ill. Comp. Stat. § 175/1 *et seq.*; Ind. Code § 5-11-5.5 *et seq.*; La. Rev. Stat. Ann. § 46:439.1 *et seq.*; Md. Code Ann., Health-Gen. § 2-601 *et seq.*; Mass. Gen. Laws ch. 12, § 5A *et seq.*; Mich. Comp. Laws § 400.601 *et seq.*; Minn. Stat. § 15C.01 *et seq.*; Mont. Code Ann. § 17-8-401 *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; N.J. Stat. Ann. § 2A:32C-1 *et seq.*; N.M. Stat. Ann. § 27-14-1 *et seq.*; N.Y. State Fin. Law § 187 *et seq.*; N.C. Gen. Stat. § 1-605 *et seq.*; Okla. Stat. tit. 63, § 5053 *et seq.*; R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tenn. Code Ann. § 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.*; and Wis. Stat. § 20.931 *et seq.*

B. That judgment be entered in Relator's favor and against Defendant in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various

schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §§ 3730(d) and 3730(h), Cal. Gov't Code § 12652(g)(4), Colo. Rev. Stat. § 25.5-4-306(4), Conn. Gen. Stat. § 17b-301e(e), Del. Code Ann. tit. 6, § 1205, D.C. Code § 2-308.15(f), Fla. Stat. § 68.085, Ga. Code Ann. § 49-4-168.2(i), Haw. Rev. Stat. § 661-27, 740 Ill. Comp. Stat. § 175/4(d), Ind. Code § 5-11-5.5-6, La. Rev. Stat. Ann. § 439.4, Md. Code Ann., Health-Gen. § 2-605, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Minn. Stat. § 15C.13, Mont. Code Ann. § 17-8-410, Nev. Rev. Stat. § 357.210, N.J. Stat. Ann. § 2A:32C-7, N.M. Stat. Ann. § 27-14-9, N.Y. State Fin. Law § 190(6), N.C. Gen. Stat. § 1-610, Okla. Stat. tit. 63, § 5053.4, R.I. Gen. Laws § 9-1.1-4(d), Tenn. Code Ann. § 71-5-183(d), Tex. Hum. Res. Code Ann. § 36.110, Va. Code Ann. § 8.01-216.7, and Wis. Stat. § 20.931(11), including without limitation (i) reinstatement of employment with no diminution of seniority, (ii) double back-pay for the period since his unlawful retaliatory termination, (iii) interest on such back-pay, and (iv) special damages, including reasonable attorneys' fees and litigation costs.

D. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars ($5,000) per claim or more than ten thousand dollars ($10,000) per claim as provided by Cal. Gov't Code § 12651(a), to the extent such penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the Delaware False Claims and Reporting Act, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the

various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each false claim as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various

schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in Haw. Rev. Stat. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Haw. Rev. Stat. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars ($5,000) as provided by Ind. Code § 5-11-5.5-2(b), to the extent such penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in La. Rev. Stat. Ann. § 46:438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by La. Rev. Stat. Ann. § 46:438.6(B)(1), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Maryland or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars ($10,000) for each false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such penalties fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relator's favor and against Defendant for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than five thousand dollars ($5,000) dollars and not more than ten thousand dollars ($10,000), plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendant's actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch 12. § 5B, to the extent such penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided as a result of Defendant's unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendant's unlawful conduct, as well as not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and Relator, as provided by §§ 400.610a(9) and 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendant's unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendant's unlawful conduct, as well as not less

than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Michigan and Relator, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in Mont. Code Ann. § 17-8-403, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to Mont. Code Ann. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in Nev. Rev. Stat. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act, pursuant to Nev. Rev. Stat. § 357.040(1), to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than and not more than the civil penalties allowed under the federal False Claims Act (31 U.S.C. § 3729 *et seq.*) for each false or fraudulent claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relator's favor and against Defendant for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4, multiplied as provided for in N.M. Stat. Ann. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

W. That judgment be entered in Relator's favor and against Defendant for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions

for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relator's favor and against Defendant for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.C. Gen. Stat. § 1-607, multiplied as provided for in N.C. Gen. Stat. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. Gen. Stat. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Okla. Stat. tit. 63, § 5053.1(B), to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. Gen. Laws § 9-1.1-3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by R.I. Gen.

Laws § 9-1,1-3(a), to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than twenty-five thousand dollars ($25,000) pursuant to Tenn. Code Ann. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in

injury to an elderly or disabled person, pursuant to Tex. Hum. Res. Code Ann. §§ 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in Wis. Stat. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Wis. Stat. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

EE. That Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

FF. That judgment be granted for Relator against Defendant for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit; and

GG. That Relator be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(a), Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: March 15, 2012

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